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“PRIME HEALTH” AND THE REGULATION OF HYBRID  
HEALTHCARE\*

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*This article examines the possible constructs behind the announcement that Amazon, Berkshire Hathaway, and JPMorgan Chase & Co. are jointly building a new healthcare entity for their employees. In this article, I provide context by discussing and comparing the healthcare ambitions of the three largest information technology companies before arguing that various forms of hybrid entities will increase their footprint in healthcare data and delivery. The core of this discussion is a thought experiment about the nature of what I term “Prime Health.” That analysis is based initially on observations about Amazon’s existing culture and business model of Amazon. Thereafter I examine both what Prime Health could and should be. I argue that it will likely go beyond the pedestrian model of a very large self-funded group insurance plan; will disintermediate traditional healthcare insurers; and attempt to bring consumers and healthcare providers together into some type of online marketplace—an updated, privatized version of managed competition. In the final parts of the article I delve into the regulatory environment that hybrid healthcare generally, and Prime Health in particular, will face. This analysis includes federal device and data protection laws, a few idiosyncratic state laws, and a brief discussion of the problems inherent in the limited regulation of hybrid healthcare entities.*

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## INTRODUCTION

Healthcare is no stranger to dramatic headlines. However, a short press release in January 2018 was not only the mother of all healthcare stories but also desperately short on detail. In a joint press release, Amazon, Berkshire Hathaway, and JPMorgan Chase & Co. announced they were founding an independent company focusing on “technology solutions that will provide U.S. employees and their families with

simplified, high-quality, and transparent healthcare at a reasonable cost.”<sup>1</sup> According to Berkshire Hathaway Chairman and CEO, Warren Buffett:

The ballooning costs of healthcare act as a hungry tapeworm on the American economy. Our group does not come to this problem with answers. But we also do not accept it as inevitable. Rather, we share the belief that putting our collective resources behind the country's best talent can, in time, check the rise in health costs while concurrently enhancing patient satisfaction and outcomes.<sup>2</sup>

Commentators and interviewees responded to this announcement with heady optimism about healthcare reform while the stock prices of traditional healthcare stakeholders came under pressure.<sup>3</sup> The *Economist* hailed the announcement with the headline “A digital revolution in health care is coming.”<sup>4</sup>

A few months before the press release, there were rumors that Amazon had a secret “skunkworks” healthcare team codenamed 1492.<sup>5</sup> But even today, there is very little information about what Amazon and its two partners—Berkshire Hathaway and JPMorgan Chase & Co.—intend, let alone whether it portends a “revolution.” We do know it will be independent of its founding companies, non-profit, and based in Boston.<sup>6</sup> Still, at the time of this writing, it doesn’t even have a name. Herein the corporate entity will be referred to as “ABJ” and the service/product as “Prime Health.”

Nevertheless, there is some evidence that Amazon and its partners are not just building a better healthcare service but are considering a novel healthcare model designed to eliminate or minimize some well-known problems with U.S. healthcare.

<sup>1</sup> Press Release, Amazon, Berkshire Hathaway & JPMorgan Chase & Co., Amazon, Berkshire Hathaway and JPMorgan Chase & Co. to Partner on U.S. Employee Healthcare (Jan. 30, 2018), [https://www.businesswire.com/news/home/20180130005676/en/Amazon-Berkshire-Hathaway-JPMorgan-Chase-partner-U.S.](https://www.businesswire.com/news/home/20180130005676/en/Amazon-Berkshire-Hathaway-JPMorgan-Chase-partner-U.S)

<sup>2</sup> *Id.*

<sup>3</sup> Carolyn Y. Johnson, *Amazon, Berkshire Hathaway and JP Morgan Chase Join Forces to Tackle Employees' Health-care Costs*, WASH. POST: WONKBLOG (Jan. 30, 2018), <https://www.washingtonpost.com/news/wonk/wp/2018/01/30/amazon-berkshire-hathaway-and-jp-morgan-chase-join-forces-to-tackle-employees-health-care-costs/?>.

<sup>4</sup> *Doctor You*, ECONOMIST, Feb. 3, 2018, at 11.

<sup>5</sup> Eugene Kim & Christina Farr, *Amazon 1492: Secret Health Tech Project*, CNBC (July 26, 2017, 5:30 PM), <https://www.cnbc.com/2017/07/26/amazon-1492-secret-health-tech-project.html>.

<sup>6</sup> Jessica Bartlett, Health Care Venture Co-Founded by Amazon to Be Based in Boston, Bos. Bus. J. (June 20, 2018, 10:09 AM), <https://www.bizjournals.com/boston/news/2018/06/20/healthcare-venture-co-founded-by-amazon-to-be.html>.

These problems include access difficulties (particularly for the very poor and the poor); high and increasing prices and costs (including insurance costs, prescription drug costs, and cost-shifting); substandard care coordination; an incoherent delivery model involving multiple types of entities and financing or reimbursement models; and severe deficiencies in data management and sharing.

At root, many of these problems are a function of friction, as multiple stakeholders exhibit inefficiencies, create indeterminacies, and create informational problems all while generally failing to coalesce with their fellow stakeholders. For a company like Amazon, which has figured out a way to reduce friction and combine its digital and physical presence, U.S. healthcare's complexity and resistance to reform must be frustrating. And, now perhaps, ABJ sees an opportunity.

This article provides a framework for understanding how the largest technology companies view healthcare and their roles in healthcare's future. I contrast their approaches and their relationships with traditional healthcare stakeholders, label them as hybrids, and contrast their healthcare interests. Amazon emerges from this analysis as a positive outlier because of its existing role as a retailer of physical healthcare goods, its unique approach to combining digital and physical products, and its participation in ABJ's ambitious healthcare financing and delivery project. I argue that Prime Health will be more than the sum of its parts and that it will attempt to remove (i.e. disintermediate) some intermediary stakeholder from the healthcare value chain, thereby establishing a new healthcare marketplace. (That is, that Prime Health will cut out certain middle persons from various healthcare transactions.) Further, I analyze how this imagined Primed Health will raise issues of over-regulation and under-regulation.

Part II provides context, discussing the businesses and likely conceptions of healthcare among the major technology companies that have been explicit about their healthcare ambitions: Apple, Alphabet, and Amazon. That discussion leads to a tentative conclusion that their healthcare plays will result in differentiated hybrid entities that combine disruptive technologies with novel approaches to brick-and-mortar businesses. Part III projects the properties of Prime Health, assuming it is based on the existing culture and business model of Amazon. Part IV, working with minimal evidence and relatively unrestrained conjecture, examines both what Prime Health *could* and *should* look like if it departs from Amazon's existing culture and business model. This part argues that it will (i) go beyond the pedestrian model of a very large self-funded group insurance plan, (ii) disintermediate traditional healthcare insurers, and (iii) attempt to bring consumers and healthcare providers together into an online marketplace (i.e. an updated, privatized version of managed competition). Part V discusses how current healthcare regulation (which was drafted

with traditional, brick-and-mortar healthcare entities in mind) will apply to these new hybrid entities, with particular attention paid to Prime Health. Part VI highlights some specific concerns about the under-regulation of high technology companies as they broaden their grip on economic activities and healthcare in particular.

## I HYBRID TYPOLOGY

The involvement of high technology companies in healthcare is not new. While some mythologize the progress of traditional health information technologies such as electronic health records,<sup>7</sup> information technology companies have been part of the health puzzle for a while, albeit without notable effect.<sup>8</sup>

Recently, however, strong evidence has surfaced that the largest technology companies are targeting healthcare with increased interest. Technology companies are investing more heavily in health-related ventures,<sup>9</sup> services such as Uber are participating in non-emergency medical transportation,<sup>10</sup> and key functions such as ICU monitoring are being outsourced to remote providers.<sup>11</sup> At the highest level, some seek to be agents of change and insert their technologies or business strategies into healthcare. While the “big three”—Apple, Amazon, and Alphabet (Google’s parent company)—have been explicit, others such as Facebook are believed to have similar ambitions.<sup>12</sup>

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<sup>7</sup> Vindell Washington et al., *The Hitech Era and the Path Forward*, 377 NEW ENG. J. MED. 904 (2017).

<sup>8</sup> See Nicolas P. Terry, *Information Technology’s Failure to Disrupt Healthcare*, 13 NEV. L.J. 722 (2013).

<sup>9</sup> Natasha Singer, *How Big Tech Is Going After Your Health Care*, N.Y. TIMES (Dec. 26, 2017), <https://www.nytimes.com/2017/12/26/technology/big-tech-health-care.html> (“In the first 11 months of [2017], 10 of the largest tech companies in the United States were involved in health care equity deals worth \$2.7 billion, up from just \$277 million for all of 2012.”).

<sup>10</sup> Ann M. Marciarille, *Uberizing Nonemergency Medical Transportation*, PRAWFSBLAWGS (Jan. 19, 2018, 8:31 PM), <http://prawfsblawg.blogs.com/prawfsblawg/2018/01/uberizing-nonemergency-medical-transportation.html>.

<sup>11</sup> See Chiedozie Udeh et al., *Telemedicine/Virtual ICU: Where Are We and Where Are We Going?*, 14 METHODIST DEBAKEY CARDIOVASCULAR J. 126 (2018).

<sup>12</sup> E.g., Christina Farr, *Facebook Sent a Doctor on a Secret Mission to Ask Hospitals to Share Patient Data*, CNBC (Apr. 5, 2018, 2:01 PM), <https://www.cnbc.com/2018/04/05/facebook-building-8-explored-data-sharing-agreement-with-hospitals.html> (examining evidence from several sources on Facebook’s desire to link their data with healthcare data to improve services).

In decoding the announcements and activities of these companies, it is clear that there is not one model of technologically-mediated care but several. While Apple, Amazon, and Google may all be seeking to disrupt, or at least transform, healthcare, their business models and strategies are quite different. As the *New York Times* notes, “[e]ach tech company is taking its own approach, betting that its core business strengths could ultimately improve people’s health.”<sup>13</sup>

As a result, these interventions into the healthcare space or even attempted disruptions of incumbents by technologically-equipped market entrants cannot be reduced to a binary. It remains unlikely that either the brick-and-mortar business typified by traditional healthcare systems or the pure technological model favored by Apple will emerge victorious. It is more probable that the conquering business will be a hybrid, as was true for their disruption of other markets. For example, Amazon built its disruptive business on a digital platform for selling books yet has now opened some physical bookstores.<sup>14</sup> Similarly, AmazonFresh began as a product category, an extension of Amazon’s delivery service,<sup>15</sup> but its strategic potential changed after the company’s purchase of the brick-and-mortar Whole Foods.<sup>16</sup>

### A. Apple

Apple is first and foremost a consumer electronics company<sup>17</sup> that builds software and hardware, particularly the iPhone. Like other smartphones, the iPhone has become “a portal for managing daily life.”<sup>18</sup> Apple software and services are designed to put the consumer in control of their information (including health information) in a trusted, secure environment.<sup>19</sup>

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<sup>13</sup> Singer, *supra* note 9, at 2.

<sup>14</sup> Jake Swearingen, *Why Is Amazon Building Brick-and-Mortar Bookstores?* N.Y. MAG.: INTELLIGENCER (June 1, 2017), <http://nymag.com/selectall/2017/06/why-is-amazon-building-bookstores.html>.

<sup>15</sup> J.J. McCorvey, *The Race Has Just Begun*, FAST COMPANY, Sept. 2013, at 68 (discussing how AmazonFresh grocery products can be purchased online and delivered along with other goods from Amazon’s non-grocery product selection).

<sup>16</sup> Nick Wingfield & Michael J. de la Merced, *Amazon to Buy Whole Foods for \$13.4 Billion*, N.Y. TIMES (June 16, 2017), <https://www.nytimes.com/2017/06/16/business/dealbook/amazon-whole-foods.html>.

<sup>17</sup> Either Apple has morphed from a computer company into a consumer electronics company or computers have become consumer electronics.

<sup>18</sup> *Surgical Intervention*, ECONOMIST, Feb. 3, 2018, at 59.

<sup>19</sup> *Id.* at 60.

Although Apple is opening medical clinics for its employees,<sup>20</sup> its primary healthcare focus is on consumer-facing hardware and software that monitors health<sup>21</sup> or empowers consumers to safely curate their own health information.<sup>22</sup> In that latter context, David Blumenthal and Aneesh Chopra argue such an approach removes patient dependency “on the bureaucracies of big health systems or on understaffed physician offices to make their own data available for further care.”<sup>23</sup> With the data liberated and under patient control, “consumer-facing applications . . . have the potential to revolutionize patient-provider interactions and empower consumers in ways never before imagined in the history of medicine.”<sup>24</sup> The Apple strategy does not seem to compete with incumbent healthcare. It creates an additional level of data, derived directly from the patient via its own apps that are secure and patient-centric. Increasingly, however, Apple is facilitating the import of data created in traditional healthcare settings into its ecosystem.<sup>25</sup> Apple is also implementing actions based on the healthcare data it collects, for example, by providing health alerts derived from such data. Progressively, therefore, the data generated or imported by Apple’s customers will resemble or become intertwined with more traditional healthcare services (and, potentially, intertwined with traditional healthcare regulation).

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<sup>20</sup> Christina Farr, *Apple Is Launching Medical Clinics to Deliver the 'World's Best Health Care Experience' to Its Employees*, CNBC (Feb. 27, 2018), <https://www.cnbc.com/2018/02/27/apple-launching-medical-clinics-for-employees.html>.

<sup>21</sup> See, e.g., Alex Webb, *Apple Is Developing an EKG Heart Monitor for Its Smartwatch*, BLOOMBERG (Dec. 21, 2017, 12:00 PM), <https://www.bloomberg.com/news/articles/2017-12-21/apple-is-said-to-develop-ekg-heart-monitor-for-future-watch>.

<sup>22</sup> See Press Release, Apple, *Apple Announces Effortless Solution Bringing Health Records to iPhone* (Jan. 24, 2018), <https://www.apple.com/newsroom/2018/01/apple-announces-effortless-solution-bringing-health-records-to-iphone/> (discussing an update to Apple’s Health app which allows users to view their medical records on their iPhone); see also Apple, *Apple Opens Health Records API to Developers* (Jun. 4, 2018), <https://www.apple.com/newsroom/2018/06/apple-opens-health-records-api-to-developers/>.

<sup>23</sup> David Blumenthal & Aneesh Chopra, *Apple’s Pact with 13 Health Care Systems Might Actually Disrupt the Industry*, HARV. BUS. REV. (Mar. 23, 2018), <https://hbr.org/2018/03/apples-pact-with-13-health-care-systems-might-actually-disrupt-the-industry>.

<sup>24</sup> *Id.*

<sup>25</sup> Lucas Mearian, *Apple’s Health Record API Released to Third-Party Developers; Is it Safe?*, COMPUTERWORLD (June 7, 2018, 3:11 AM), <https://www.computerworld.com/article/3279746/apple-ios/apples-health-record-api-released-to-third-party-developers-is-it-safe.html> (discussing Apple’s API which allows users to transfer their electronic health records to iPhone and share between providers).

### B. Alphabet

Alphabet takes an orthogonal approach, concentrating on patient and pre-patient data and using AI to predict, *inter alia*, risk-factors.<sup>26</sup> The company has invested heavily in numerous health technology companies.<sup>27</sup> Verily, Alphabet's primary healthcare subsidiary, is developing tools and devices that collect and analyze health data to improve interventions and care management, typically in partnership with existing stakeholders.<sup>28</sup> Recently Alphabet announced a re-organization and consolidation of its healthcare properties into a new Google Health unit.<sup>29</sup>

DeepMind, Alphabet's UK-based AI subsidiary, has shown a particular interest in health data.<sup>30</sup> Indeed, DeepMind's close working relationship with Royal Free NHS Foundation Trust, in which the latter supplied DeepMind with the clinical records of 1.6 million patients, drew a stern rebuke from the UK Information Commissioner's office.<sup>31</sup> Notwithstanding Alphabet's generalist and data-driven approach, it does have one subsidiary concentrating on direct care initiatives: Cityblock. This subsidiary creates community-based clinics ("Neighborhood Hubs") in underserved urban areas.<sup>32</sup>

Looking at the future of healthcare through the lenses of these and other companies, we can imagine at one end of the spectrum vertically integrated legacy companies (incumbents) exemplified by the combination of Aetna (the third largest U.S. health insurer) and CVS (the largest U.S. pharmacy and pharmacy benefit manager).<sup>33</sup> At the other end of the spectrum, Apple is building relationships with

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<sup>26</sup> *Surgical Intervention*, *supra* note 18.

<sup>27</sup> Jillian D'Onfro, *Alphabet's Bets on Health Tech Are Paying Off as Portfolio Companies Go Public*, CNBC (Mar. 30, 2018, 1:44 PM), <https://www.cnbc.com/2018/03/30/alphabet-gv-life-sciences-and-health-investments-going-public.html>.

<sup>28</sup> VERILY, <https://verily.com> (last visited Oct. 18, 2018).

<sup>29</sup> Christina Farr, *The New Google Health Unit Is Absorbing Health Business from DeepMind*, Alphabet's AI Research Group, CNBC (Nov. 13, 2018, 11:15 AM), <https://www.cnbc.com/2018/11/13/google-health-unit-absorbs-deepmind-health.html>.

<sup>30</sup> *About DeepMind Health*, DEEPMIND, <https://deepmind.com/applied/deepmind-health/about-deepmind-health/> (last visited Oct. 18, 2018).

<sup>31</sup> *Royal Free - Google DeepMind Trial Failed to Comply with Data Protection Law*, ICO (Jul. 3, 2017), <https://ico.org.uk/about-the-ico/news-and-events/news-and-blogs/2017/07/royal-free-google-deepmind-trial-failed-to-comply-with-data-protection-law/>.

<sup>32</sup> *Our Story*, CITYBLOCK, <https://www.cityblock.com/about> (last visited Oct. 18, 2018).

<sup>33</sup> Brian Fung, *CVS's \$69 Billion Merger with Aetna Is Approved in Deal that Could Transform Health-Care Industry*, WASH. POST (Oct. 10, 2018), <https://www.washingtonpost.com/>



health researchers and large providers but essentially focusing on consumer products and secure management of patient-controlled health information. In the middle, but closer to Apple, is Alphabet: data-focused but still a hybrid because of the deep relationships it is building with researchers and providers to gain access to their health data.

### C. Amazon

As it did for Amazon Web Services (“AWS”), Amazon may well start Prime Health with the goal of being its “first and best customer.”<sup>34</sup> But, thereafter, it is much more likely it will look to scale and attract other employers and eventually even individuals. It has to do so in order to fulfill its prime directive, extracting profit from all transactions.

A common misperception is that the Prime Health partners have no ambition beyond leveraging their buying power to cut better deals with healthcare incumbents.<sup>35</sup> Indeed, it has been argued that of the big three, Apple and Alphabet will have a greater short-term impact than will Prime Health. Here, the argument is that the initial, internal roll-out of Prime Health will only cover ABJ’s approximately one million employees, whereas Apple and Alphabet may be quicker to make their health insights available to hundreds of millions of external customers.<sup>36</sup>

Others will take that course. For example, Cisco Systems, Intel, and Walmart have all built direct relationships with providers.<sup>37</sup> In contrast, it is simply not Amazon’s way to take such a reactively pedestrian path.

The Amazon pathology around this idea of its own first and best customer is quite consistent. It launched a sophisticated and scalable data system to track its own customers and logistics (Amazon was the first and best customer of AWS) before

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technology/2018/10/10/justice-department-approves-cvss-billion-merger-with-insurance-giant-aetna/? (discussing the CVS-Aetna merger).

<sup>34</sup> Ben Thompson, *The Amazon Tax*, STRATECHERY (Mar. 15, 2016), <https://stratechery.com/2016/the-amazon-tax/> (using the term “first and best customer” to describe the practice wherein Amazon built AWS for internal use first before making AWS available to customers externally).

<sup>35</sup> See, e.g., Robert Langreth & Zachary Tracer, *Buffett-Bezos Health Plan Will Hinge on Buying Power, Technology*, BLOOMBERG (Jan. 30, 2018, 10:39 AM), <https://www.bloomberg.com/news/articles/2018-01-30/surprise-bid-to-upend-health-care-rests-on-buying-power-tech>.

<sup>36</sup> *Surgical Intervention*, *supra* note 18.

<sup>37</sup> Caroline Humer, *Fed Up with Rising Costs, Big U.S. Firms Dig into Healthcare*, REUTERS (Jun. 11, 2018, 6:07 AM), <https://www.reuters.com/article/us-usa-healthcare-employers-insight/fed-up-with-rising-costs-big-u-s-firms-dig-into-healthcare-idUSKBN1J70ZZ>.

opening up AWS to outsiders and, not incidentally, many billions in annual revenue.<sup>38</sup> Similarly, Amazon is investing in aircraft and trucks to build its own delivery service infrastructure. Initially, Amazon will be its own first and best customer and no doubt find itself with leverage in negotiations with UPS and FedEx,<sup>39</sup> but inevitably thereafter, third parties will be able to ship via “Amazon Parcel” or however it will be branded. Finally, AmazonFresh lacked a first and best customer within the Amazon portfolio—the solution? Amazon purchased Whole Foods, “the first-and-best customer that will instantly bring its grocery efforts to scale.”<sup>40</sup> Regarding its healthcare ambitions, circumstantial evidence shows that Amazon is exploring aspects of traditional healthcare such as prescription drug distribution.<sup>41</sup>

One of the difficulties in discerning the properties of, much less answering structural or delivery questions about, Prime Health is that it is difficult to see where Amazon’s internal healthcare needs end and Prime Health’s ambitions begin. For example, Prime Health could be a relatively modest effort based on a very large, self-funded ABJ group health plan with “innovation” restricted to somewhat pedestrian (albeit worthy) build-outs of company-owned employee health clinics.<sup>42</sup> That model is supported by some recent hiring by Amazon (rather than Prime Health). For example, Amazon hired a former U.S. FDA chief health informatics

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<sup>38</sup> Jason Del Rey, *Amazon’s AWS and Advertising Businesses Are Fueling Its Retail Dominance*, RECODE (Apr. 26, 2018, 6:55 PM), <https://www.recode.net/2018/4/26/17286316/amazon-jeff-bezos-amzn-q1-earnings-revenue-stock-aws-advertising>; Ron Miller, *How AWS Came to Be*, TECHCRUNCH (July 2, 2016), <https://techcrunch.com/2016/07/02/andy-jassys-brief-history-of-the-genesis-of-aws/>.

<sup>39</sup> Laura Stevens, *Amazon to Launch Delivery Service That Would Vie with FedEx, UPS*, WALL ST. J. (Feb. 9, 2018), <https://www.wsj.com/articles/amazon-to-launch-delivery-service-that-would-vie-with-fedex-ups-1518175920>.

<sup>40</sup> Ben Thompson, *Amazon’s New Customer*, STRATECHERY (June 19, 2017), <https://stratechery.com/2017/amazons-new-customer/>.

<sup>41</sup> See, e.g., Carolyn Y. Johnson, *What Amazon Could Do to the Business of Selling Prescription Drugs*, WASH. POST (May 17, 2017), <https://www.washingtonpost.com/news/wonk/wp/2017/05/17/what-amazon-could-do-to-the-business-of-selling-prescription-drugs/>; Robert Langreth & Spencer Soper, *This Is How Amazon Could Invade the Pharmacy*, BLOOMBERG (Nov. 7, 2017, 10:10 AM), <https://www.bloomberg.com/news/articles/2017-11-07/six-ways-amazon-could-upend-the-pharmacy-business>.

<sup>42</sup> See Christina Farr, *Amazon Has Plans to Open Its Own Health Clinics for Seattle Employees*, CNBC (Aug. 9, 2018, 12:46 PM), <https://www.cnbc.com/2018/08/09/amazon-plans-primary-care-clinics-employees.html>; see also Christina Farr, *Amazon Just Hired a Top Seattle Doctor Who Ran a Network of Health Clinics*, CNBC (Jan. 19, 2018, 5:14 PM), <https://www.cnbc.com/2018/01/19/amazon-hired-seattles-martin-levine-from-iora-to-add-to-health-group.html>.

officer<sup>43</sup> and a well-known cardiologist.<sup>44</sup> At the moment, it is impossible for outsiders to see the vector between Amazon’s own healthcare ambitions and Prime Health (i.e. what it is building for its employees internally compared with what it is building for users externally). It is possible that Amazon itself does not yet know.

Neither an ambition to build Prime Health nor the supposition that it will likely adopt a hybrid construct completely answer questions such as what Prime Health will look like or how it will function. For example, will Amazon, in the vein of its Whole Foods acquisition, purchase brick-and-mortar providers such as hospitals?<sup>45</sup> Additionally, while some technological “disruptions” of healthcare (for example, Apple enabling individuals to curate their own health information) will add new layers to the existing healthcare industry without immediately threatening incumbents, Amazon initiatives are typically unfriendly to incumbents. Their entrance suggests there will be some net losers. The next two sections address these structural questions, first by keying in on some of the cultural and business practices that define Amazon and, second, by examining the various ways that Prime Health could be structured and how it could deliver access to care (or even provide actual care).

## II

### HOW THE AMAZON MODEL MAY FRAME PRIME HEALTH

The next two parts use a thought experiment to analyze Prime Health, which proceeds as follows. Part III highlights the foundational properties of Amazon that are likely to migrate to Prime Health. It relies on identifiable properties of the Amazon business model (“Amazon’s DNA”) such as data-leveraging and being customer-driven. Part IV expands that vision, imagining what Prime Health *could* or *should* achieve if not constrained by Amazon’s existing culture and business model.

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<sup>43</sup> Christina Farr, *Amazon is Hiring a Former FDA Official to Work on Its Secretive Health Tech Business*, CNBC (Mar. 16, 2018, 5:14 PM), <https://www.cnbc.com/2018/03/16/amazon-hiring-taha-kass-hout-former-fda-cto.html>.

<sup>44</sup> Christina Farr, *Amazon Hires a Star Cardiologist to Help Its Push into Health*, CNBC, (Aug. 20, 2018, 2:10 PM), <https://www.cnbc.com/2018/08/20/amazon-hires-star-cardiologist-maulik-majmudar.html?>

<sup>45</sup> Nicolas P. Terry, *Prime Health: Should Amazon Purchase a Hospital Chain?*, MEDIUM (July 30, 2017), <https://medium.com/@nicolasterry/prime-health-should-amazon-purchase-a-hospital-chain-7a322d1ad0ec>.

Since the pioneering work of Kenneth Arrow, it has been well established that healthcare fails to obey basic market rules.<sup>46</sup> In part, this explains the political interest in more radical disruptions of healthcare, with internally-driven reforms or externally-fashioned, market-driven reforms deemed as unlikely.<sup>47</sup> U.S. businesses built around well-functioning markets who shop for healthcare or health insurance for their employees are likely confused or at least frustrated by an ecosystem strewn with path-dependent practices and misaligned incentives. Not surprisingly, therefore, mainstream businesses generally have not expanded into healthcare while technology-harnessing disruptive businesses have continued their relentless targeting of even the most unlikely brick-and-mortar incumbents.<sup>48</sup>

However, Amazon, often to the befuddlement of financial analysts, is a very different type of company and somewhat counter intuitively may prove to be a formidable competitor in healthcare. For example, Amazon “in an accelerated and innovative way . . . continues to invest in areas of growth at the expense of profitability, something most other retailers (and other firms) can’t afford to do.”<sup>49</sup> And Amazon is also a patient company, “willing and able to build [Internet] businesses with the patience that will be necessary to wait for the old order to collapse.”<sup>50</sup> These characteristics support the imagining of Prime Health as a long game disruption of U.S. healthcare.

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<sup>46</sup> Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941 (1963).

<sup>47</sup> See, e.g., Yoni Blumberg, *70% of Americans Now Support Medicare-For-All—Here's How Single-Payer Could Affect You*, CNBC (Aug. 28, 2018, 1:05 PM), <https://www.cnbc.com/2018/08/28/most-americans-now-support-medicare-for-all-and-free-college-tuition.html>.

<sup>48</sup> See, e.g., Carrie Hojnicky, *How Casper Disrupted the Mattress Industry*, ARCHITECTURAL DIG. (Mar. 21, 2017), <https://www.architecturaldigest.com/story/how-startup-casper-disrupted-the-mattress-industry>; Warren Shoulberg, *What's Next for Mattress Firm After Bankruptcy and Putting 700 Stores to Sleep?*, FORBES, (Oct. 5, 2018, 12:54 PM), <https://www.forbes.com/sites/warrenshoulberg/2018/10/05/whats-next-for-mattress-firm-after-bankruptcy-and-putting-700-stores-to-sleep/#69906b8e5328>.

<sup>49</sup> See Michael K. Spencer, *W\*F is Amazon?*, MEDIUM (Nov. 1 2017), [https://medium.com/@Michael\\_Spencer/wtf-is-amazon-future-of-tech-34802913dc9e](https://medium.com/@Michael_Spencer/wtf-is-amazon-future-of-tech-34802913dc9e); see also Shira Ovide, *How Amazon's Bottomless Appetite Became Corporate America's Nightmare*, BLOOMBERG (Mar. 14, 2018), <https://www.bloomberg.com/graphics/2018-amazon-industry-displacement/>.

<sup>50</sup> Ben Thompson, *Amazon Health*, STRATECHERY (Jan. 31, 2018), <https://stratechery.com/2018/amazon-health/>.

### A. Data Driven

Data may or may not be the new oil<sup>51</sup> or the new coal.<sup>52</sup> However, it is clear that the promise of integrating data is a major driver of merger and acquisition activity. As Wendy Epstein noted in the context of the CVS-Aetna combination, “in a world where consumer costs have dominated the discussion, it is at least worth thinking more about the impact that the integration of payor and provider data might have.”<sup>53</sup> Further, according to Dan Mendelson, “[a] lot of the basic wiring of the health care system is now complete—a result of federal investment and lower technology prices. The need now is to harness the power of analytics to improve care. . . . [T]his drives mergers and acquisition.”<sup>54</sup> Data is also an important demand-side driver. Patients lacking knowledge and control is a major problem in our current healthcare system; empowering them with access to data may provide such knowledge and control, thereby increasing consumer demand for healthcare.<sup>55</sup> Prime Health’s recent hiring of COO Jack Stoddard, who has a strong track record in digital health, further suggests the extent to which Prime Health will be data-driven.<sup>56</sup>

### B. Combining the Digital with the Physical

The “big three” technology companies already possess almost unimaginable amounts of customer data, some of it health information and much of it medically-inflected data. They have also built some of the most sophisticated analytics and logistics platforms. Further, Amazon broke new ground by combining the digital and physical in a way never before seen.<sup>57</sup> As Michael J. Coren notes, “Amazon’s

<sup>51</sup> *The World's Most Valuable Resource Is No Longer Oil; Regulating the Data Economy*, ECONOMIST, May 6, 2017, at 9.

<sup>52</sup> Alex Hern, *Why Data Is the New Coal*, GUARDIAN (Sept. 27, 2016, 6:26 AM), <https://www.theguardian.com/technology/2016/sep/27/data-efficiency-deep-learning>.

<sup>53</sup> Wendy N. Epstein, *The CVS/Aetna Deal: The Promise in Data Integration*, BILL OF HEALTH (Dec. 13, 2017), <http://blogs.harvard.edu/billofhealth/2017/12/13/the-cvsaetna-deal-the-promise-in-data-integration/>.

<sup>54</sup> Robert J. Samuelson, Opinion, *Is This the Future of Health Care?*, WASH. POST (Nov. 1, 2017), [https://www.washingtonpost.com/opinions/is-this-the-future-of-health-care/2017/11/01/45dcc4dc-bf1b-11e7-8444-a0d4f04b89eb\\_story.html?](https://www.washingtonpost.com/opinions/is-this-the-future-of-health-care/2017/11/01/45dcc4dc-bf1b-11e7-8444-a0d4f04b89eb_story.html?hpid=hp_hp-top-table-main-healthcare%3Ahomepage%2Fstory&hpid=hp_hp-top-table-main-healthcare%3Ahomepage%2Fstory)

<sup>55</sup> *Doctor You*, *supra* note 4.

<sup>56</sup> Christina Farr, *The Amazon-Berkshire-JPM Health Venture Led by Atul Gawande Has a COO: Jack Stoddard*, CNBC (Sept. 4, 2018, 2:28 PM), <https://www.cnbc.com/2018/09/04/amazon-berkshire-jpm-health-venture-hires-jack-stoddard-coo.html>.

<sup>57</sup> Michael J. Coren, *There's Precedent for Amazon Competing with So Many Companies. It Doesn't End Well.*, QUARTZ (Oct. 28, 2017), <https://qz.com/1107328/theres-precedent-for-amazon-competing-with-so-many-companies-it-doesnt-end-well/>.

unprecedented logistics and delivery infrastructure, paired with access to personal data about Americans' purchasing habits, means it is unique in the history of global commerce."<sup>58</sup>

It has been more than a decade since Steven Spear argued that healthcare should adopt the technologies and practices of successful businesses and "tightly couple the process of doing work with the process of learning to do it better as it's being done."<sup>59</sup> Yet, how many healthcare providers have heeded or implemented that message? In contrast, any Prime Health service providers would become customers of key strategies and technologies, rapidly improving areas where healthcare institutions suffer from under-investment or lack of scale, such as procurement, secure IT, and data analytics.

Amazon already possesses many healthcare properties, of which Prime Health could potentially take advantage.<sup>60</sup> For example, Amazon already sells medical supplies and equipment,<sup>61</sup> offers one-hour delivery on some OTC drugs in Seattle,<sup>62</sup> sells prescription drugs in Japan,<sup>63</sup> has reportedly been acquiring expertise in selling prescription drugs in the U.S.,<sup>64</sup> and recently acquired PillPack, an online pharmacy specializing in pre-sorted medication doses.<sup>65</sup> Further, in Whole Foods, Amazon has a collection of strategically placed locations that are already being fitted with pickup and return lockers for Amazon customers. Without a doubt, these could be expanded to include brick-and-mortar pharmacies or clinics. The company even holds a patent

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<sup>58</sup> *Id.*

<sup>59</sup> Steven J. Spear, *Fixing Healthcare from the Inside, Today*, HARV. BUS. REV., Sept. 2005, at 1.

<sup>60</sup> Terry, *supra* note 45.

<sup>61</sup> *Department of Medical Supplies & Equipment*, AMAZON, <https://www.amazon.com/Medical-Supplies-Equipment-Health-Care/b?ie=UTF8&node=3775161> (last visited Nov. 3, 2018).

<sup>62</sup> *Introducing Prime Now Free 2-Hour Delivery*, BARTELL DRUGS, <https://www.bartelldrugs.com/services/primenow/> (last visited Nov. 3, 2018) (offering non-prescription drugs through Prime Now).

<sup>63</sup> Shusuke Murai, *Amazon Launches Same-Day Delivery Service for Food and Medicine*, JAPAN TIMES (Apr. 19, 2017), <https://www.japantimes.co.jp/news/2017/04/19/business/amazon-launches-same-day-delivery-service-for-food-and-medicine/#.XCaNGVxKg2w>.

<sup>64</sup> See Christina Farr, *Amazon is Hiring People to Break into the Multibillion-Dollar Pharmacy Market*, CNBC (May 16, 2017, 8:23 PM), <https://www.cnbc.com/2017/05/16/amazon-selling-drugs-pharmaceuticals.html> (discussing the variety of actions Amazon has taken to develop pharmaceutical industry expertise).

<sup>65</sup> Press Release, Amazon, Amazon to Acquire PillPack (Jun. 28, 2018), <https://www.businesswire.com/news/home/20180628005614/en/Amazon-Acquire-PillPack>.

for “anticipatory package shipping,” meaning they can ship goods to consumers before such goods are ordered, potentially reducing the costs and delays associated with the online market.<sup>66</sup> If Amazon fully deploys to Prime Health its properties in the healthcare space, Prime Health could fundamentally alter the industry.

### C. Customer-Facing

Just as it is unimaginable that Prime Health would transmit data using fax machines, “the cockroach of American medicine,”<sup>67</sup> it is also hard to believe it would tolerate brick-and-mortar anachronisms. For example, Prime Health surely would have no tolerance for waiting rooms that “put [] a high cost on a medical provider’s time while valuing the patient’s time at essentially zero.”<sup>68</sup>

Amazon continually works on the customer experience.<sup>69</sup> As an organization, it deploys considerable resources to discover and correct barriers to growth (or other “invisible asymptotes”<sup>70</sup>), such as consumer dislikes. It also has a culture of high standards and continual improvement. According to Amazon CEO Jeff Bezos:

One thing I love about customers is that they are divinely discontent. Their expectations are never static—they go up. It’s human nature. . . . People have a voracious appetite for a better way, and yesterday’s ‘wow’ quickly becomes today’s ‘ordinary.’ . . . I sense that the same customer empowerment phenomenon is happening broadly across everything we do at Amazon and most other industries as well.

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<sup>66</sup> See Coren, *supra* note 57; see also Method and Sys. for Anticipatory Package Shipping, U.S. Patent No. 8,615,473 (filed Aug. 24, 2012).

<sup>67</sup> Sarah Kliff, *The Fax of Life: Why American Medicine Still Runs on Fax Machines*, VOX (Jan. 12, 2018, 3:53 PM), <https://www.vox.com/platform/amp/health-care/2017/10/30/16228054/american-medical-system-fax-machines-why>.

<sup>68</sup> A. Gary Shilling, *Health Care’s Waiting Room Problem*, FORBES (Apr. 20, 2016), <https://www.forbes.com/sites/investor/2016/04/20/health-cares-waiting-room-problem/#6d4e5b9f514b>.

<sup>69</sup> See, e.g., Eric Feinberg, *How Amazon Is Investing in Customer Experience by Reimagining Retail Delivery*, FORBES (Jan. 4, 2018, 9:00 AM), <https://www.forbes.com/sites/forbescommunicationscouncil/2018/01/04/how-amazon-is-investing-in-customer-experience-by-reimagining-retail-delivery/#1fb846412c2e>.

<sup>70</sup> See Eugene Wei, *Invisible Asymptotes*, REMAINS OF THE DAY (May 22, 2018), <http://www.eugenewei.com/blog/2018/5/21/invisible-asymptotes> (discussing how Amazon’s investment in customer-focused research uncovered consumer dislike for paying shipping fees; by “eliminating” shipping fees with Amazon Prime, the company drastically raised their growth asymptote).

You cannot rest on your laurels in this world. Customers won't have it.<sup>71</sup>

In contrast, healthcare stakeholders continue to disagree over the importance of consumer-patient satisfaction.<sup>72</sup>

Amazon also has some intriguing customer-facing assets that have been built on top of and cemented the Prime membership lock-in. Echo devices, which allow access to Prime products, are now installed in millions of homes. It should be relatively simple to add new “Alexa skills” that respond to health inquiries and medical emergencies.<sup>73</sup> Also, because Echo-Alexa is a platform, its voice commands are now tightly integrated with myriad home automation products. For example, imagine if Prime Health were to build a team of first responders. When Prime Health first responders arrive at a Prime customer's home, they could request that its front door be remotely unlocked and house lights turned on. To many, this is a dystopian vision, but Amazon has convinced its most loyal Prime customers that it deserves their trust either because of an instrumental trade-off between privacy and convenience or the dubious proposition that Amazon does not sell data to third parties and merely exploits data for its own purposes. Amazon also sells the Echo Look,<sup>74</sup> a fashion-oriented body camera, and the Echo Show,<sup>75</sup> a video communication device. Little re-tooling should be required to make these the basis

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<sup>71</sup> Letter from Jeff Bezos, Chief Exec. Officer, Amazon.com, Inc., to Amazon's Shareholders (Apr. 18, 2018) (on file with the SEC), *available at* <https://www.sec.gov/Archives/edgar/data/1018724/000119312518121161/d456916dex991.htm>.

<sup>72</sup> See Paul Rosen, *The Patient as Consumer and the Measurement of Bedside Manner*, NEJM CATALYST (Mar. 20, 2017), <https://catalyst.nejm.org/patient-satisfaction-consumer-measurement-bedside-manner/> (discussing research which suggests that physicians, at least compared to service providers in other industries, place relatively less weight on the importance of customer satisfaction and experience); see also Augusta Meill & Gianna Ericson, *The Trouble with Treating Patients as Consumers*, HARV. BUS. REV. (Jan. 9, 2012), <https://hbr.org/2012/01/the-trouble-with-treating-pati>.

<sup>73</sup> See generally *Alexa Skills*, AMAZON, <https://www.amazon.com/b?node=13727921011> (last visited Oct. 31, 2018).

<sup>74</sup> *Echo Look*, AMAZON, [https://www.amazon.com/dp/B0186JAEWK/ref=fs\\_ods\\_hx](https://www.amazon.com/dp/B0186JAEWK/ref=fs_ods_hx) (last visited Oct. 31, 2018).

<sup>75</sup> *Echo Show*, AMAZON, [https://www.amazon.com/dp/B01J24C0TI/ref=fs\\_ods\\_kt](https://www.amazon.com/dp/B01J24C0TI/ref=fs_ods_kt) (last visited Oct. 31, 2018).



for an effective telemedicine platform. Recently, Amazon has even announced that its Alexa AI engine will be acquiring some basic emotional awareness.<sup>76</sup>

#### *D. Reading the Gawande Tea Leaves*

Notwithstanding early reports that ABJ was experiencing difficulty in finding its first CEO,<sup>77</sup> in June 2018, ABJ announced that Dr. Atul Gawande, the well-known surgeon, writer, and academician, will lead the new company.<sup>78</sup>

There are several reformist themes readily discernible from Gawande’s books, popular press, and peer-reviewed literature. His best known writing on the healthcare system appeared in three articles in the *New Yorker* from 2010-12: *The Cost Conundrum*,<sup>79</sup> *Cowboys and Pit Crews*,<sup>80</sup> and *Big Med* (aka the Cheesecake Factory).<sup>81</sup> Gawande’s themes are relatively consistent: over-utilization (particularly of surgical procedures and procedures with debatable cost-effectiveness), the need for reimbursement to be based on quality not quantity, inadequate attention paid to the actual needs and satisfaction of patients, lack of care coordination needing to be met with teamwork, increased standardization and checklists, and a recognition of “the reality that medicine’s complexity has exceeded our individual capabilities as doctors.”<sup>82</sup> In medical literature, he is probably best known for his (and his research center, Ariadne Lab’s) work in designing the World Health Organization surgical

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<sup>76</sup> Tom Simonite, *Amazon Wants Alexa to Hear Your Whispers and Frustration*, WIRED (Sept. 20, 2018), <https://www.wired.com/story/amazon-alexa-upgrades-whisper-alexa-guard/> (“[Amazon] is experimenting with giving Alexa a rudimentary form of emotional awareness, enabling it to listen for the sound of frustration in a person’s voice.”).

<sup>77</sup> Christina Farr, *The Bezos-Buffett-Dimon Joint Venture to Save Health Care Is Struggling to Find a CEO*, CNBC (May 16, 2018), <https://www.cnbc.com/2018/05/16/amazon-berkshire-jmp-health-group-struggling-to-find-ceo.html?>.

<sup>78</sup> Press Release, Amazon, Berkshire Hathaway & JPMorgan Chase & Co., Amazon, Berkshire Hathaway and JPMorgan Chase Appoint Dr. Atul Gawande as Chief Executive Officer of Their Newly-Formed Company to Address U.S. Employee Healthcare (June 20, 2018), <https://www.businesswire.com/news/home/20180620005744/en/Amazon-Berkshire-Hathaway-JPMorgan-Chase-Appoint-Dr..>

<sup>79</sup> Atul Gawande, *The Cost Conundrum*, NEW YORKER, June 1, 2009.

<sup>80</sup> Atul Gawande, *Cowboys and Pit Crews*, NEW YORKER (May 26, 2011), <https://www.newyorker.com/news/news-desk/cowboys-and-pit-crews>.

<sup>81</sup> Atul Gawande, *What Big Medicine Can Learn from the Cheesecake Factory*, NEW YORKER (Aug. 13, 2012), <https://www.newyorker.com/magazine/2012/08/13/big-med>.

<sup>82</sup> Gawande, *supra* note 80.

checklist<sup>83</sup> and its validation studies both globally<sup>84</sup> and in an important South Carolina study.<sup>85</sup> Just after his announcement as ABJ's CEO, while speaking at the annual meeting of America's Health Insurance Plans, Gawande opined that surgery is the single largest healthcare cost.<sup>86</sup>

Gawande seems to hold relatively mainstream views touched on by other centrist reformers,<sup>87</sup> such as advocating for reasonable cost containment strategies. (To a certain degree, some fully vertically-integrated providers already implement such strategies.<sup>88</sup>) Gawande was a defender of the ACA's incremental approach to cost containment,<sup>89</sup> earning a rebuke from Alain Enthoven for defending Congress' "unmistakable signal that it is unable or unwilling to control health expenditures and the fiscal deficit."<sup>90</sup>

Other than suggesting a centrist approach and a sensitivity towards health equity, we know little about how Gawande will approach his leadership role at Prime Health. That said, a commitment to patient safety, patient satisfaction, and concerns about tertiary healthcare costs suggest Gawande is a leader well-versed in the current challenges facing healthcare in the U.S. and someone compatible with Amazon's DNA.

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<sup>83</sup> See *Surgery: WHO Safe Surgery Checklist*, ARIANDE LABS, <https://www.ariadnelabs.org/areas-of-work/safe-surgery-checklist/> (last visited Oct. 31, 2018).

<sup>84</sup> Alex B. Haynes et al., *A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population*, 360 NEW ENG. J. MED. 491, 491 (2009).

<sup>85</sup> See Alex B. Haynes et al., *Mortality Trends After a Voluntary Checklist-Based Surgical Safety Collaborative*, 266 ANNALS SURGERY 923, 923 (2017); see also George Molina et al., *Perception of Safety of Surgical Practice Among Operating Room Personnel from Survey Data Is Associated with All-Cause 30-day Postoperative Death Rate in South Carolina*, 266 ANNALS SURGERY 658, 658 (2017).

<sup>86</sup> Deena Beasley, *Surgery, Not Pharma, Is Biggest Healthcare Cost Worry: Gawande*, INS. J. (June 22, 2018), <https://www.insurancejournal.com/news/national/2018/06/22/493065.htm>.

<sup>87</sup> See, e.g., Donald Berwick et al., *The Triple Aim: Care, Health, and Cost*, 27 HEALTH AFF. 759, 759-69 (2008); Donald Berwick et al., *No Toyota yet, but a Start*, 35 MODERN HEALTHCARE 18, 18-19 (2005).

<sup>88</sup> See, e.g., JESSE PINES ET AL., BROOKINGS INST., KAISER PERMANENTE-CALIFORNIA: A MODEL FOR INTEGRATED CARE FOR THE ILL AND INJURED (2015), [https://www.brookings.edu/wp-content/uploads/2016/07/KaiserFormatted\\_150504RH-with-image.pdf](https://www.brookings.edu/wp-content/uploads/2016/07/KaiserFormatted_150504RH-with-image.pdf).

<sup>89</sup> Atul Gawande, *Testing, Testing*, NEW YORKER, Dec. 14, 2009, at 34.

<sup>90</sup> Alain C. Enthoven, *Would Reform Bills Control Costs? A Response to Atul Gawande*, HEALTH AFF. (Dec. 22, 2009), <https://www.healthaffairs.org/doi/10.1377/hblog20091222.003279/full/>.

### III WHAT PRIME HEALTH *COULD* OR *SHOULD* BE

This section builds on the foundational properties described above. It is more speculative, relying on the work of business analysts, previous disruptions by technology companies, and the potential for disintermediation of some healthcare incumbents. Unlike Part III, this Part IV imagines what Prime Health could look like if not constrained by Amazon’s existing culture and business model. Questions about what Prime Health *could* be are interwoven with what it *should* be. The conceit of this article is that Prime Health could be built off the disintermediation of some stakeholders and the commoditization of the products and services of others.<sup>91</sup> Therein also lies the normative point; what Prime Health *should* be is an attempt to demonstrate vitality and innovation in the employer role in providing access to healthcare services.

These questions include the likely customers and where the enterprise will identify structural and delivery deficiencies that can be improved upon. There is also a fundamental question of whether Prime Health will be based upon some existing construct or will be built from whole cloth.<sup>92</sup> According to the *Economist*, “[t]here are two broad routes into health care. The first is doing business with hospitals and health-care companies in the existing system . . . . A second route is for tech firms to use their various platforms to create entirely new channels through which medical care can be delivered to patients.”<sup>93</sup> These are accurate descriptions of the disruption-lite we are seeing from Alphabet and Apple, with the former tending to build data relationships with existing providers on top of which it can build analytics products and the latter tending to build new channels and tools atop of existing clinical and research relationships.

#### A. Strategic Options

There are some imperfect parallels to an expansive sketch of Prime Health. For example, the idea of commoditizing healthcare products and services is somewhat reflected in the announced strategy of large healthcare networks to create

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<sup>91</sup> Thompson, *supra* note 50.

<sup>92</sup> See, e.g., Drew Altman, *Don't Overhype the New Health Care Venture*, AXIOS (Feb. 8, 2018), <https://www.axios.com/dont-overhype-new-health-care-venture-88b62e53-f56b-4a5e-8ba9-c96266902747.html>.

<sup>93</sup> *Surgical Intervention*, *supra* note 18.

their own drug company to manufacture off-patent drugs.<sup>94</sup> Essentially, the providers intend to commoditize off-patent drugs to counter the practice of pharmaceutical companies continuing to sell such drugs at high prices because of “a reduction in the number of suppliers, consolidation of production volumes, and a concentration of market pricing power.”<sup>95</sup>

Vertically-integrated providers may provide another preview (albeit imperfect) of what Prime Health could theoretically look like. Some non-governmental, vertically-integrated providers, such as affordable care organizations (“ACOs”), report positive results, although generally with regard to quality rather than reduced costs.<sup>96</sup> Overall, evidence about the performance of fully vertically-integrated providers is mixed.<sup>97</sup> An additional parallel can be drawn to the Veterans Health Administration (“VA”), a fully vertically-integrated provider. The VA, for obvious reasons, “owns” its consumers and it purchases healthcare goods and services (their clinical staff are employees) without using intermediaries. The VA uses comparative effectiveness research to determine clinical practices and which drugs to include in its formulary.<sup>98</sup> It is certainly within the realm of probability that Prime Health would adopt a limited formulary like the VA does<sup>99</sup> or like Massachusetts has proposed for its Medicaid program.<sup>100</sup>

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<sup>94</sup> Reed Abelson & Katie Thomas, *Fed Up With Drug Companies, Hospitals Decide to Start Their Own*, N.Y. TIMES, Jan. 18, 2018, at B1.

<sup>95</sup> *Leading U.S. Health Systems Announce Plans to Develop a Not-for-profit Generic Drug Company*, INTERMOUNTAIN HEALTHCARE (Jan. 18, 2018), <https://intermountainhealthcare.org/news/2018/01/leading-us-health-systems-announce-plans-to-develop-a-not-for-profit-generic-drug-company/>.

<sup>96</sup> See, e.g., Wenke Hwang et al., *Effects of Integrated Delivery System on Cost and Quality*, 19 AM. J. MANAGED CARE e175, e178-82 (2013).

<sup>97</sup> See Austin Frakt, *The Performance of Integrated Delivery Systems*, ACADEMYHEALTH (July 20, 2016), <https://www.academyhealth.org/node/2151> (discussing several studies showing that integrated health service networks often fail to reduce costs while only occasionally improving quality of care).

<sup>98</sup> See David Atkins et al., *The Veterans Affairs Experience: Comparative Effectiveness Research in A Large Health System*, 29 HEALTH AFF. 1906, 1906-07 (2010); see also GRETCHEN A. JACOBSON ET AL., CONG. RESEARCH SERV., RL33802, PHARMACEUTICAL COSTS: A COMPARISON OF DEPARTMENT OF VETERANS AFFAIRS (VA), MEDICAID, AND MEDICARE POLICIES 8-14 (2007).

<sup>99</sup> U.S. DEPT. VETERANS AFFAIRS, VHA FORMULARY MANAGEMENT PROCESS (2009), <https://www.pbm.va.gov/PBM/directive/vhadirective.pdf>.

<sup>100</sup> See Katie Gudiksen, *State Medicaid Programs Are a Tool to Address Rising Drug Costs*, SOURCE ON HEALTHCARE PRICE & COMPETITION: SOURCE BLOG (May 8, 2018),

### B. The Customers

The ABJ parent companies have a national presence and employ approximately one million people in worldwide.<sup>101</sup> A fundamental question is whether ABJ will build Prime Health exclusively for its own employees or build it out as a generally available product. If the endeavor hues to Amazon’s traditional practices, Prime Health will begin with ABJ employees (its first and best customers<sup>102</sup>) and then extend outwards, maybe to other large employers and ultimately even to individuals.

In June 2018, at an event planned before his appointment at ABJ, Atul Gawande gave a lengthy interview at the Aspen Ideas Festival.<sup>103</sup> He spoke about the demographics of ABJ employees, beginning with Amazon’s fulfillment center workers:

Most of [Amazon’s fulfillment center workers], people who probably are there only about a year or so. These are people who have very unstable health care, been in and out . . . . Then you get to JPMorgan Chase, where their largest employment group are bank tellers. So you’re talking about people at the 30th, 40th, 50th percentile

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<http://sourceonhealthcare.org/state-medicaid-programs-are-a-tool-to-address-rising-drug-costs/>. In June 2018, CMS refused Massachusetts’ Medicaid waiver request. *See* Letter from Angela D. Garner, Dir., Div. Sys. Reform Demonstrations, Ctrs. Medicare & Medicaid Servs., to Daniel Tsai, Assistant Sec’y & Dir. MassHealth, Mass. Exec. Office Health & Human Servs. (Oct. 23, 2018) (on file with Ctrs. Medicare & Medicaid Servs.), *available at* <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma/ma-masshealth-ca.pdf>.

<sup>101</sup> In 2017, Amazon employed 566,000 people worldwide. *See* Kurt Schlosser, *Amazon Now Employs 566,000 People Worldwide—a 66 Percent Jump from a Year Ago*, GEEKWIRE (Feb. 1, 2018), <https://www.geekwire.com/2018/amazon-now-employs-566000-people-worldwide-66-percent-jump-year-ago/>. As of June 2018, JPMorgan Chase & Co. employed 252,539 people. *See* Company Profile for JPMorgan Chase & Co., FORBES, <https://www.forbes.com/companies/jpmorgan-chase/#6a4f553f9fa9> (last updated June 6, 2018). As of November 2017, Berkshire Hathaway employed approximately 377,291 people. *See* Company Profile for Berkshire Hathaway, Inc., BLOOMBERG, <https://www.bloomberg.com/research/stocks/private/snapshot.asp?privcapId=255251> (last updated Nov. 20, 2018).

<sup>102</sup> *See supra* Part I.C.

<sup>103</sup> A Conversation with Surgeon, Author, and Researcher Atul Gawande, Aspen Institute (June 23, 2018) [hereinafter Conversation with Atul Gawande], <https://www.aspenideas.org/sites/default/files/transcripts/A%20Conversation%20with%20Surgeon%2C%20Author%2C%20and%20Researcher%20Atul%20Gawande.pdf>.

of income. They fall between the people who get Medicaid and the people who get Medicare.<sup>104</sup>

Gawande was also sensitive to health inequities present in our current system, noting how middle income individuals pay “taxes for people to get Medicaid. That’s better coverage than they could ever get. No co-pays, no premiums, no deductibles.”<sup>105</sup> Finally, he reflected on the growing problem of underinsurance, stating that “typically, in private sector employment, you’re getting up to \$1,000, \$2,000 deductibles these days.”<sup>106</sup>

It is certainly tempting to believe that a company led by Dr. Gawande—someone with a sophisticated understanding of the societal costs of access stratification and the detrimental impact of health insurance policies’ declining actuarial values—has ambitions beyond its own employees. If Prime Health were to expand beyond its own employees, it would likely be facilitated by Amazon’s existing “ownership” of more than 100 million “Prime” members.<sup>107</sup> Among those are persons with lower incomes who are subsidized by Amazon,<sup>108</sup> a perhaps tenuous link to the Affordable Care Act (ACA) model of making individual insurance affordable on the exchanges.<sup>109</sup>

### C. Friction and Intermediaries

U.S. healthcare has become a zero-sum game, shifting costs rather than creating new value.<sup>110</sup> This does not have to be the case. Healthcare incumbents could expand into new businesses that are not directly related to clinical care, such as fitness and healthcare management.<sup>111</sup> To an extent, this is the market that Apple is beginning to dominate, at least for more affluent consumers. Such consumers spend additional, discretionary “healthcare” dollars to have their health information

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<sup>104</sup> *Id.*

<sup>105</sup> *Id.*

<sup>106</sup> *Id.*

<sup>107</sup> Bezos, *supra* note 71.

<sup>108</sup> Nick Wingfield, *Pitching Deal, Amazon Bids for Shoppers on a Budget*, N.Y. TIMES, Mar. 8, 2018, at B2 (discussing discounted Amazon Prime membership for low-income Americans).

<sup>109</sup> 26 U.S.C. § 36B (2012) (establishing tax credits designed to help low-income individuals and families afford health insurance purchased through the Health Insurance Marketplace).

<sup>110</sup> See, e.g., Michael E. Porter & Elizabeth Teisberg, *Redefining Competition in Health Care*, HARV. BUS. REV., June 2004, at 66.

<sup>111</sup> Dave Chase, *Overcoming Healthcare Organizations' Dangerous Zero Sum Thinking*, FORBES (July 12, 2015, 4:45 PM), <https://www.forbes.com/sites/davechase/2015/07/12/overcoming-healthcare-organizations-dangerous-zero-sum-thinking/#7f22aef16fa4>.

collected by an Apple Watch and securely stored on an iPhone. In this scenario, Apple is unlikely to pull revenue away from traditional healthcare businesses, although it may disrupt the watch and direct-to-consumer (“DTC”) medical device markets.

However, Prime Health is likely to play out in a zero-sum environment. If Prime Health is going to succeed, some other healthcare businesses are going to suffer or fail, just as booksellers, network television, department stores, and shopping malls have failed over the last twenty years because of competition from Amazon.<sup>112</sup>

The U.S. healthcare system has many idiosyncratic properties, most of which either increase cost or make it harder to decrease costs. Many of these properties can be attributed to accidental intermediaries or rent-seekers who arguably add little value to the supply chain that connects patients to healthcare services and products. In contrast, technology companies thrive on eliminating friction from transactions and reducing barriers between the consumer and the goods or services they want.<sup>113</sup>

Employers fall into the “accidental intermediary” category. One of healthcare’s original sins was the placement of employers in the middle of healthcare markets, a mistake made soon after the Second World War ended. U.S. healthcare has been path dependent ever since. After all, how many employees want their employers involved in their wellness or healthcare? Why, pre-ACA, should an employer’s business decision about the structuring of a health insurance benefit (self funded vs. fully funded) be determinative of whether state or federal law applies? Even when employers are not involved, their ghosts interfere. For example, the historical tying of health insurance to employment is in part responsible for the recent movement to making work a requirement for Medicaid.<sup>114</sup>

These negative externalities have been offset somewhat by the preeminence of group health insurance in reach, cost, and coverage due to the strong bargaining position of employers. As the percentage of Americans covered by employer health

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<sup>112</sup> See, e.g., Lydia DePillis, *It’s Amazon’s World. We Just Live in It.*, CNN (Oct 4, 2018), <https://www.cnn.com/2018/10/03/tech/amazon-effect-us-economy/index.html>.

<sup>113</sup> David Pogue, *Technology’s Friction Problem*, 306 SCI. AM. 28, 28 (2012).

<sup>114</sup> See generally MaryBeth Musumeci et al., *Medicaid and Work Requirements: New Guidance, State Waiver Details and Key Issues*, HENRY J. KAISER FAMILY FOUND. (Jan. 16, 2018), <https://www.kff.org/medicaid/issue-brief/medicaid-and-work-requirements-new-guidance-state-waiver-details-and-key-issues/>.

insurance continues to gradually decline,<sup>115</sup> the premiums paid by employees continue to rise.<sup>116</sup> Moreover, copays and other out-of-pocket (“OOP”) cost-shifting mechanisms reduce actuarial value, creating a cohort of underinsured employees.<sup>117</sup> The continuing role of employers seems less of a positive. Indeed, the fact that employers can deduct the cost of employer-sponsored health insurance (part of the “accident” in employer involvement in healthcare) arguably encourages overspending on healthcare<sup>118</sup> and led to the ACA’s high-cost plan tax (the so-called “Cadillac Tax”).<sup>119</sup> Whether the high-cost plan tax is progressive or regressive is still under debate.<sup>120</sup> Politically unpopular, the tax has been repeatedly delayed<sup>121</sup> and may never be applied.

Notwithstanding the federal government’s promotion of health information technologies<sup>122</sup> or the promise of Apple and Google’s forays into health-related gadgets and data analytics respectively, healthcare has proven difficult to disrupt.<sup>123</sup> According to disruption guru Clay Christensen and his colleagues, “[t]hird-party reimbursement systems sap motivation for innovation—particularly disruptive

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<sup>115</sup> ELISE GOULD, ECON. POL’Y INST., A DECADE OF DECLINES IN EMPLOYER-SPONSORED HEALTH INSURANCE COVERAGE 2 (2012), <https://www.epi.org/files/2012/bp337.pdf>.

<sup>116</sup> Zachary Tracer, *Rising Health-Insurance Costs Are Eating Into Employees' Paycheck Gains*, BLOOMBERG (Sept. 19, 2017, 12:30 PM), <https://www.bloomberg.com/news/articles/2017-09-19/rising-health-insurance-costs-blunt-employees-paycheck-gains>.

<sup>117</sup> SARAH R. COLLINS ET AL., COMMONWEALTH FUND, HOW WELL DOES INSURANCE COVERAGE PROTECT CONSUMERS FROM HEALTH CARE COSTS? 4-6 (2017), [https://www.commonwealthfund.org/sites/default/files/documents/\\_\\_\\_media\\_files\\_publications\\_issue\\_brief\\_2017\\_oct\\_collins\\_underinsured\\_biennial\\_ib.pdf](https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_issue_brief_2017_oct_collins_underinsured_biennial_ib.pdf).

<sup>118</sup> William H. Frist, *Obamacare's 'Cadillac Tax' Could Help Reduce the Cost Of Health Care*, FORBES (Feb. 26, 2014, 7:37 AM), <https://www.forbes.com/sites/theapothecary/2014/02/26/obamacares-cadillac-tax-could-help-reduce-the-cost-of-health-care/#4b3ed54c3989>.

<sup>119</sup> *Id.*; 26 U.S.C. § 4980I (2012).

<sup>120</sup> Sherry Glied & Adam Striar, *Looking Under the Hood of the Cadillac Tax*, 15 COMMONWEALTH FUND 1, 4-6 (2016).

<sup>121</sup> See, e.g., Bruce Japsen, *Big Employers Win Delay for Obamacare's Cadillac Tax Once Again*, FORBES (Jan. 23, 2018, 4:30 PM), <https://www.forbes.com/sites/brucejapsen/2018/01/23/big-lobbies-and-employers-once-again-win-delay-for-obamacares-cadillac-tax/#1afdfd513ed4>.

<sup>122</sup> See, e.g., Nicolas P. Terry, *Pit Crews with Computers: Can Health Information Technology Fix Fragmented Care?*, 14 HOUS. J. HEALTH L. & POL’Y 129, 139-40, 162-64 (2014).

<sup>123</sup> See generally Terry, *supra* note 8, at 754, 756.



innovation—out of the system.”<sup>124</sup> It is therefore possible that the predicate for Prime Health disruption is to remove third-party reimbursement from the picture.

Collectively, health insurers have reported annual revenues of more than three-quarters of a trillion dollars since 2013<sup>125</sup> and continue to report record profits.<sup>126</sup> Intuitively, they should function to reduce costs. However, Elisabeth Rosenthal notes that health insurers have very little incentive to negotiate better prices with suppliers of healthcare services and products.<sup>127</sup> What, then, is their value as intermediaries or infomediaries?

Developments in the 1990s hinted at a positive answer. For a few years, managed care reversed the trend of healthcare inflation as consumers moved to health maintenance organizations (“HMOs”).<sup>128</sup> However, backlash from consumers and physicians soon put a stop to this reversal,<sup>129</sup> as healthcare continued to devour more and more of the economy, except during a short blip during the Great Recession.<sup>130</sup> A general summary of the failure is this: managed care attacked

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<sup>124</sup> CLAYTON M. CHRISTENSEN ET AL., *SEEING WHAT’S NEXT: USING THE THEORIES OF INNOVATION TO PREDICT INDUSTRY CHANGE* 197 (2004).

<sup>125</sup> JACK CURRAN, *IBISWORLD, HEALTH & MEDICAL INSURANCE IN THE US* 38 (2018).

<sup>126</sup> Bertha Coombs, *As Obamacare Twists in Political Winds, Top Insurers Made \$6 Billion (Not That There Is Anything Wrong with That)*, CNBC (Aug. 5, 2017, 9:39 AM), <https://www.cnbc.com/2017/08/05/top-health-insurers-profit-surge-29-percent-to-6-billion-dollars.html>.

<sup>127</sup> Elisabeth Rosenthal, *An American Sickness: How Healthcare Became Big Business and How You Can Take It Back* 20-21 (2017).

<sup>128</sup> Alain C. Enthoven & Sara J. Singer, *The Managed Care Backlash and the Task Force in California*, 17 HEALTH AFF. 95, 96-97 (1998).

<sup>129</sup> See Robert J. Blendon et al., *Understanding the Managed Care Backlash*, 17 Health Aff. 80, 83, 90 (1998); see also *Managed Care: What Went Wrong? Can It Be Fixed?*, STAN. GRADUATE SCH. BUS. (Nov. 1, 1999), <https://www.gsb.stanford.edu/insights/managed-care-what-went-wrong-can-it-be-fixed>.

<sup>130</sup> Amitabh Chandra et al., *Is This Time Different? The Slowdown in Health Care Spending*, Brookings Papers on Econ. Activity, Fall 2013, at 272-74.

volume despite the fact that the real issue, of course, was (and remains) price,<sup>131</sup> including drug prices,<sup>132</sup> hospital charges,<sup>133</sup> and physician salaries.<sup>134</sup>

Historian Christy Ford Chapin argues that “[t]he problem with American health care is not the care. It’s the insurance.”<sup>135</sup> Health insurers’ failure to control prices (for which they are not necessarily responsible) explains two provisions in the ACA: (1) the Medical-Loss Ratio (“MLR”)<sup>136</sup> and (2) the Independent Payment Advisory Board (“IPAB”).<sup>137</sup> Further, the *Washington Post* Editorial Board noted, in reference to the IPAB, that “[e]very bit of waste is some companies’ profit, and the industry wasn’t going to let it go without a fight—though of course it pretended to be fighting on behalf of patients.”<sup>138</sup> This sentiment can also be applied to the MLR. The MLR was designed to force insurers to spend a greater percentage of premium income on healthcare rather than administrative costs or executive salaries.<sup>139</sup> Few ACA provisions have had as much vitriol spilled on them as the IPAB. IPAB was a potential check on Medicare overspending that, if successful, would likely have influenced private insurance spending. It was despised by healthcare companies<sup>140</sup> and finally laid to rest in the 2018 Spending Bill.<sup>141</sup> In its obituary, the *Washington*

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<sup>131</sup> Gerard F. Anderson et al., *It’s the Prices, Stupid: Why the United States Is SO Different from Other Countries*, 22 HEALTH AFF. 89, 90-103 (2003).

<sup>132</sup> Robert Langreth, *Drug Prices*, Bloomberg (Jan. 25, 2016), <https://www.bloomberg.com/quicktake/drug-prices>.

<sup>133</sup> Tara Bannow, *Report Finds Hospitals Drive Overall Healthcare Price Growth*, MOD. HEALTHCARE (Apr. 13, 2018), <http://www.modernhealthcare.com/article/20180413/NEWS/180419947>.

<sup>134</sup> Dean Baker, *The Problem of Doctors’ Salaries*, POLITICO, (Oct. 25, 2017, 5:03 AM), <https://www.politico.com/agenda/story/2017/10/25/doctors-salaries-pay-disparities-000557>.

<sup>135</sup> Christy F. Chapin, *How Health Care Went Wrong*, N.Y. TIMES, June 19, 2017, at A19.

<sup>136</sup> Patient Protection and Affordable Care Act § 2718, 42 U.S.C. § 300gg-18 (2012).

<sup>137</sup> *Id.* § 3403, 42 U.S.C. § 1395kkk-1 (repealed 2018).

<sup>138</sup> Editorial Board, *The So-called Obamacare Death Panel Meets Its Unfortunate End*, WASH. POST, (Feb. 9, 2018), [https://www.washingtonpost.com/opinions/the-so-called-death-panel-meets-its-unfortunate-end/2018/02/09/b4c3a23c-0cfd-11e8-8b0d-891602206fb7\\_story.html](https://www.washingtonpost.com/opinions/the-so-called-death-panel-meets-its-unfortunate-end/2018/02/09/b4c3a23c-0cfd-11e8-8b0d-891602206fb7_story.html).

<sup>139</sup> *Explaining Health Care Reform: Medical Loss Ratio (MLR)*, HENRY J. KAISER FAMILY FOUND. (Feb. 29, 2012), <https://www.kff.org/health-reform/fact-sheet/explaining-health-care-reform-medical-loss-ratio-mlr/>.

<sup>140</sup> Sahil Kapur, *Why Republicans Are Fighting to Repeal Obama’s Medicare Cost-Cutting Board*, TALKING POINTS MEMO (Feb. 28, 2012, 12:29 AM), <https://talkingpointsmemo.com/dc/why-republicans-are-fighting-to-repeal-obama-s-medicare-cost-cutting-board>.

<sup>141</sup> Mike DeBonis & Erica Werner, *Brief Government Shutdown Ends as Trump Signs Spending Bill*, WASH. POST: POWERPOST (Feb. 9, 2018), <https://www.washingtonpost.com/>

*Post* opined that “[t]he IPAB . . . represented Congress’s peak effort at serious spending restraint on health care, which is probably why it had few champions and a long list of enemies. Now, before ever beginning its work, IPAB has been smothered.”<sup>142</sup>

#### *D. Managed Competition: HillaryCare for the Digital Age*

According to business analyst Ben Thompson, “the most important consequence of the Internet . . . was the reduction of the cost of distribution to effectively zero.”<sup>143</sup> Amazon had a novel approach to the cost of distribution. It made the cost of distribution *appear* to be free by having its customers pre-pay through Prime. At that point, big box stores, grocery stores, bookstores, etc., lost their distribution monopolies. According to Thompson, once a distribution monopoly is lost, disruption occurs. First, Internet-based companies can take over the ownership of customers. Second, once products are no longer protected by the cost-based distribution monopoly they are easier to commodify.<sup>144</sup> It is that commodification of health services and products that may be at the core of the Prime Health construct.

The lack of insurer interest in engaging in meaningful cost containment and the absence of government negotiation<sup>145</sup> combine to keep healthcare prices high. High margins and unhelpful intermediaries are anathema to Amazon’s view of commerce. After all, as noted by Malcolm Harris, “[t]he world’s biggest store doesn’t use suggested retail pricing; it sets its own.”<sup>146</sup> Disintermediating insurers could be the first step in a “disintermediate-commoditize-build out” strategy.

As to the second step, Thompson speculates that Prime Health will build out “interfaces” for its employees to access existing healthcare services (presumably treatment, care, equipment, pharmacies, etc.). Then it will build “infrastructure for

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powerpost/congress-passes-sweeping-budget-bill-ending-brief-shutdown/2018/02/09/6021367e-0d69-11e8-8890-372e2047c935\_story.html?.

<sup>142</sup> Editorial Board, *supra* note 138.

<sup>143</sup> Ben Thompson, *The Great Unbundling*, STRATECHERY (Jan. 18, 2017), <https://stratechery.com/2017/the-great-unbundling/>.

<sup>144</sup> *Id.*

<sup>145</sup> See 42 U.S.C. § 1395w–111(i) (2012); see also Tony Abraham, *Azar Says Admin 'Does Not Believe in' Medicare Drug Price Negotiations*, HEALTHCARE DIVE (May 16, 2018), <https://www.healthcaredive.com/news/azar-says-admin-does-not-believe-in-medicare-drug-price-negotiations/523678/>.

<sup>146</sup> Malcolm Harris, *The Singular Pursuit of Comrade Bezos*, MEDIUM (Feb. 15, 2018), <https://medium.com/s/story/the-singular-pursuit-of-comrade-bezos-3e280baa045c>.

those healthcare suppliers, requiring them to serve Amazon's employees using a standard interface."<sup>147</sup> That infrastructure will then morph into a marketplace where services compete to serve the employees. Essentially, if these hypotheses play out, Prime Health will have disintermediated health insurance companies and set the stage for the commoditization of healthcare services.<sup>148</sup>

Once health insurers are disintermediated, Prime Health will be free to build the marketplace of its choice. At first sight, ABJ may take the Obama-era construct of the Health Insurance Marketplace, designed to link patients to insurers (the traditional *sine qua non* for healthcare),<sup>149</sup> but re-engineer it to link patients to providers. However, the Prime Health construct arguably may go further. If ABJ is seeking to be an agent of change and provide a structure whereby those providing healthcare services at all levels compete for ABJ dollars, the Prime Health construct may resemble the Clinton managed competition plan of the 1990s more than the managed care of the 1980s or the ACA's individual exchange marketplaces.<sup>150</sup> In this iteration, the non-profit Prime Health would replace the federal government in "managing" the competition. And if successful, the strategy will lead to the third step, building out Prime Health as a product to be offered outside of ABJ. ABJ's founding companies would be the first and maybe best customers of Prime Health, but eventually not the only ones.

### *E. Delivery and Services*

Assuming the existence of some form of marketplace, questions arise as to the extent ABJ will build out its own services and how disaggregated the non-ABJ services offered on the marketplace will be. For example, it is obvious that Amazon already has efficient interfaces to somewhat commoditize OTC pharmaceuticals, and Amazon seems to be expanding into Rx pharmaceuticals. Equally, Amazon is

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<sup>147</sup> Thompson, *supra* note 50.

<sup>148</sup> *Id.*

<sup>149</sup> Patient Protection and Affordable Care Act § 1311(b), 42 U.S.C. § 18031 ("Each State shall . . . establish an American Health Benefit Exchange . . ."). *See generally What is the Health Insurance Marketplace?*, U.S. DEP'T HEALTH & HUM. SERVS., <https://www.hhs.gov/answers/affordable-care-act/what-is-the-health-insurance-marketplace/index.html> (last visited Nov. 1, 2018).

<sup>150</sup> Robert Pear, *Clinton's Health Plan: The Overview; Congress is Given Clinton Proposal for Health Care*, N.Y. TIMES, Oct. 28, 1993, at A1. *See generally* Alain C. Enthoven, *The History and Principles of Managed Competition*, 12 HEALTH AFF. 24 (1993).

already an established seller of Durable Medical Equipment (“DME”).<sup>151</sup> After these are established, the difficult question will be what to build and what to outsource in terms of services.

One answer would be to outsource the entire services bundle: primary, secondary, tertiary, and quaternary care.<sup>152</sup> This is an approach increasingly favored by large employers. For example, General Motors has contracted directly with the Henry Ford Health System to offer a healthcare option for its non-union employees under which the hospital system will provide all services.<sup>153</sup> As part of its “Centers of Excellence” program, Walmart contracted with the Cleveland Clinic Heart & Vascular Institute for some tertiary and quaternary services (heart, transplant, and spine care) for its employees.<sup>154</sup>

However, these relationships, like other direct-care models, are not as disruptive as would first appear. In these models, health insurers are still used as intermediaries, providing Administrative Services Only (“ASO”) in much the same way as in fully-funded employer-provided group insurance.<sup>155</sup>

Accordingly, Prime Health is unlikely to follow a simple outsourcing model. ABJ already has considerable negotiating weight and would not need to build a new non-profit corporate structure to execute such a strategy. The answer could be partial outsourcing, building out primary care through either free-standing or Whole Foods-based clinics,<sup>156</sup> and using an ASO model for higher tier services. This also feels like a half-hearted attempt at change that fails to reflect Amazon’s DNA. In the end, the purchase of a hospital chain or some other conventional healthcare asset is possible, if not probable.<sup>157</sup>

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<sup>151</sup> *Durable Medical Equipment*, AMAZON, <https://www.amazon.com/Durable-Medical-Equipment/b?ie=UTF8&node=10287908011> (last visited Oct. 22, 2018).

<sup>152</sup> See generally Trisha Torrey, *Primary, Secondary, Tertiary, and Quaternary Care*, VERYWELLHEALTH (Sep. 18, 2018), <https://www.verywellhealth.com/primary-secondary-tertiary-and-quaternary-care-2615354> (defining primary, secondary, tertiary, and quaternary care).

<sup>153</sup> See Anna W. Mathews, *GM Cuts Different Type of Health-Care Deal*, WALL ST. J. (Aug. 6, 2018, 9:52 PM), <https://www.wsj.com/articles/gm-cuts-different-type-of-health-care-deal-15335821211>.

<sup>154</sup> Brie Zeltner, *Walmart to Send Employees to Cleveland Clinic for Heart Care*, PLAIN DEALER, Oct. 12, 2012, at B2.

<sup>155</sup> See generally ANDREW AUSTIN & THOMAS L. HUNGERFORD, CONG. RESEARCH SERV., R40834, *THE MARKET STRUCTURE OF THE HEALTH INSURANCE INDUSTRY* 22, 28, 36 (2010).

<sup>156</sup> See Thompson, *supra* note 40.

<sup>157</sup> See generally Terry, *supra* note 45.

*F. Caveats*

Prime Health could head in many different directions. Certainly, there are many issues and possible hurdles to monitor. The weakest link in the disintermediate-commoditize-build out model is the second—persuading those who sell high margin healthcare products and services to enter the Prime Health “trap.” This will be challenging, especially as the likely endgame is that their products or services will be commodified (or at least their competition will be “managed”). After all, unlike the German healthcare systems, there is no government mandate that regional providers negotiate as a unit.<sup>158</sup> Some trend lines could play into ABJ’s hands. Increased premiums, escalating OOP costs, and the rise of limited benefit health plans could make healthcare increasingly unaffordable for consumers. Alternatively, there may be a point at which the federal government successfully caps its healthcare expenditures by reducing Medicare services and converting Medicaid to block grants. In short, there are scenarios where having Amazon pick up excess capacity could be attractive to service and product suppliers. Waiting for this moment is where Amazon’s renowned patience may come in to play.

Another issue is over-utilization. A primary motive behind moving towards value-based care and away from fee-for-service reimbursement<sup>159</sup> is to move towards consumers “pulling” necessary and patient-centric services and away from physicians “pushing” services (i.e. provider-induced consumption).<sup>160</sup> In its search to make the consumer purchasing friction-free, Amazon has built an array of consumer-facing tools (i.e. Prime, Subscribe & Save, Dash Buttons, Echo devices, etc.) that are designed to encourage consumers to buy (i.e. pull) more and more products. To control utilization ABJ will need to mimic the re-conceptualization currently being asked of healthcare and tweak its algorithms to move from quantity to value.

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<sup>158</sup> Reinhard Busse & Miriam Blümel, *Health Systems in Transition*, 16 GER.: HEALTH SYS. REV. 1, 44 (2014) (describing the German system wherein physicians accredited to treat patients under the German statutory health insurance scheme are organized into mandatory regional associations).

<sup>159</sup> See e.g., Michael E. Porter et al., *Redesigning Primary Care: A Strategic Vision to Improve Value by Organizing Around Patients’ Needs*, 32 HEALTH AFF. 516 (2013).

<sup>160</sup> See generally Mark Graban, *#Lean: Clarifying Push, Pull, and Flow in a Hospital; the Patient “Pulls,”* LEAN BLOG (Feb. 24, 2014), <https://www.leanblog.org/2014/02/flow-push-and-pull-in-a-hospital/> (“‘Pull’ is the concept of basically building in response to actual customer demand . . . Pull reduces costs, improves quality, and makes sure the customer gets what they want, when they need it, in the right quantities.”).

No doubt Prime Health is developing alternative strategies and its strategic focus will likely adapt and shift over time. It is, however, difficult to imagine an Amazon-linked product that does not focus on consumer satisfaction, extensively leverage data, build out its own profit centers to replace services it has historically paid for, and reduce transactional friction.

#### IV REGULATING HYBRID HEALTHCARE

The past decade or so has witnessed an interesting race: whether healthcare providers would become technology-driven businesses more quickly than technology companies would learn how to provide healthcare services.<sup>161</sup> Increasingly, it seems that the technology companies will win that race. Healthcare technologies, from apps, to robotics, to AI are developing far faster than conventional healthcare can reinvent itself. At the same time, technology companies do not have to deal with innovation-sapping third-party reimbursement. Nor have technology companies had to cope with the complex regulatory structures faced by healthcare insurers, providers, and researchers.<sup>162</sup>

As already noted, the major technology companies investing heavily in healthcare are choosing different strategies, stressing different types of technologies (for example, apps rather than AI), and concentrating on different markets (for example, consumers rather than healthcare entities).<sup>163</sup> Whatever the technology-conventional healthcare “mix” they settle on, these technology companies will likely be operating some type of hybrid healthcare entities.

This evolving hybrid typology raises some interesting regulatory questions. The assumption is that the current mixture of federal and state regulatory frameworks will apply, although often without success.

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<sup>161</sup> See generally Nicolas P. Terry, *Appification, AI, and Healthcare’s New Iron Triangle*, 20 J. HEALTH CARE L. & POL’Y 117, 178-79 (2018).

<sup>162</sup> See Robert I. Field, *Why is Health Care Regulation So Complex?*, 33 PHARMACY AND THERAPEUTICS 607 (2008).

<sup>163</sup> See *supra* Part I.

### *A. Applicability of Federal Law*

#### *1. Drug and Device Regulation*

As discussed above, there is little reason to believe that ABJ will enter the pharmaceutical production space (primarily because of research and development and intellectual property costs), although it might be interested in the distribution of generics made by others. It is more likely that ABJ will look to reduce Prime Health drug costs by disintermediating not only insurers but also pharmacy benefit managers and leveraging its purchasing power to create a cost-effective formulary. As such, ABJ will need to comply with state pharmacy licensure regulations,<sup>164</sup> an area in which Amazon has expertise through its experience with drugstore.com<sup>165</sup> and its current pharmacy properties.<sup>166</sup>

Devices, however, may be a different matter. Amazon designs and sells an array of intelligent assistant products<sup>167</sup> for use inside and outside of the home.<sup>168</sup> Alexa's AI engine is now incorporated in 20,000 devices manufactured by a diverse set of companies, from home thermostats, to alarm systems, to automobiles.<sup>169</sup> In the near future it is likely to find its way into more advanced products such as home robots.<sup>170</sup>

Intelligent assistants are unlikely to be a core part of Prime Health's initial roll-out (the priority should be the marketplace). It is hard, however, to imagine that technologically-mediated care will not be a major part of Prime Health. That raises the likelihood that Alexa-enabled devices will start processing health data. These devices could make physician appointments, request simple prescription renewals, prompt medication adherence, and compile competitive, value-driven offers for

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<sup>164</sup> See e.g., *Information for Pharmacists, Pharmacies, and Pharmacy Technicians*, TEXAS STATE BOARD OF PHARMACY, <https://www.pharmacy.texas.gov/Licensing.asp> (last visited Oct. 22, 2018).

<sup>165</sup> Taylor Soper, *Walgreens to Shut Down Drugstore.com, 4 Years After \$429M Acquisition*, GEEKWIRE, (July 28, 2016, 10:14 AM), <https://www.geekwire.com/2016/walgreens-shut-drugstore-com-4-years-429m-acquisition/>.

<sup>166</sup> See Spear, *supra* note 59.

<sup>167</sup> See Bezos, *supra* note 71.

<sup>168</sup> Scot Hornick & Shri Santhanam, *How Smart Speakers Are Poised to Reinvent the Travel Industry*, HARV. BUS. REV. (Aug. 7, 2018), <https://hbr.org/2018/08/how-smart-speakers-are-poised-to-reinvent-the-travel-industry>.

<sup>169</sup> Ben F. Rubin, *Amazon's Alexa Assistant Now Works with Over 20K Devices*, CNET (Sept. 1, 2018, 6:41 AM), <https://www.cnet.com/news/amazon-alexa-assistant-is-now-in-20k-devices/>.

<sup>170</sup> See generally Terry, *supra* note 161.



surgical interventions. To the extent that Alexa-enabled devices are used to process health data, they may fall within the purview of the Food, Drug, and Cosmetic Act (FDCA), which defines a “device,” in part, as an instrument “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man.”<sup>171</sup> This is to say that Alexa-enabled devices will likely cross the line that separates consumer devices from FDA-regulated medical devices at some point.

As per FDA-issued guidance, the FDA exercises discretion with regard to very low risk devices and has typically excluded from regulation many fitness devices and some mobile medical apps.<sup>172</sup> The 21st Century Cures Act of 2016 formally extended that exclusion to some fitness software.<sup>173</sup> However, neither that reform nor the reissued draft guidance on app software<sup>174</sup> is likely to protect Amazon from a “device” characterization if Alexa is medicalized.

Finally, a recent initiative, the FDA’s Precertification (Pre-Cert) Program, is designed to better align regulatory and technology iteration cycles by using a surrogate device approval based on approving manufacturers and their safety-testing protocols.<sup>175</sup> Other healthcare hybrids, including Apple and Verily, are part of that program; Amazon is not.<sup>176</sup> Amazon signaling interest in Pre-Cert would signal how Alexa’s AI may be deployed within Prime Health.

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<sup>171</sup> Federal Food, Drug, and Cosmetic Act § 201(h), 21 U.S.C. § 321(h)(2) (2012).

<sup>172</sup> See generally Nicolas P. Terry, *Mobile Health*, 147 CHEST J. 1429 (2015); Nicholas P. Terry & Tracy D. Gunter, *Regulating Mobile Mental Health Apps*, 36 BEHAV. SCI. L. 136 (2018).

<sup>173</sup> 21st Century Cures Act § 3060, 21 U.S.C. § 360j(o).

<sup>174</sup> U.S. FOOD & DRUG ADMIN., CHANGES TO EXISTING MEDICAL SOFTWARE POLICIES RESULTING FROM SECTION 3060 OF THE 21ST CENTURY CURES ACT: DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2017), <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587820.pdf>.

<sup>175</sup> See generally *Digital Health Software Precertification (Pre-Cert) Program*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medicaldevices/digitalhealth/digitalhealthprecertprogram/default.htm> (last updated Sept. 27, 2018); Nathan G. Cortez et al., *Questions About The FDA’s New Framework For Digital Health*, HEALTH AFF.: HEALTH AFF. BLOG (Aug. 16, 2017), <https://www.healthaffairs.org/doi/10.1377/hblog20170816.061554/full/>.

<sup>176</sup> See *Digital Health Software Precertification (Pre-Cert) Program*, *supra* note 175.

## 2. Data Protection

Amazon has avoided serious scrutiny of its data practices even while other major digital companies such as Facebook have been rife with scandal.<sup>177</sup> While Amazon shares data with a limited number of third parties and mines customer data to make purchase recommendations, so far Amazon seems to view customer data as a closely held asset rather than something to be sold.<sup>178</sup> The primary reason Amazon does not have a data protection problem has less to do with its data policies than it does with the fact that, at least in the U.S., it (along with Facebook, Google, and Apple) exists in a severely under-regulated space.<sup>179</sup> In broad terms, companies holding vast stores of consumer data are essentially unregulated so long as they comply with their own privacy policies.<sup>180</sup>

Unlike consumer data regulation, U.S. data protection for health information is relatively robust.<sup>181</sup> The Privacy and Security Rules promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) broadly apply to both traditional healthcare providers and their business associates holding individually identifiable health information.<sup>182</sup> Subject to some exceptions, the HIPAA Privacy Rule prohibits the sharing of personal health information with those outside the

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<sup>177</sup> See, e.g., Dylan Curran, *Are you ready? Here is all the data Facebook and Google have on you*, GUARDIAN (Mar. 28, 2018, 6:00 AM), <https://www.theguardian.com/commentisfree/2018/mar/28/all-the-data-facebook-google-has-on-you-privacy#img-1>; Hillary Grigoris, *9 Things to Know About Facebook Privacy and Cambridge Analytica*, DIGITAL TRENDS (Apr. 5, 2018, 8:06 AM), <https://www.digitaltrends.com/social-media/what-facebook-users-should-know-about-cambridge-analytica-and-privacy/>; Alyssa Newcomb, *A Timeline of Facebook's Privacy Issues—and its Responses*, NBC NEWS (Mar. 24, 2018, 7:02 AM), <https://www.nbcnews.com/tech/social-media/timeline-facebook-s-privacy-issues-its-responses-n859651>.

<sup>178</sup> Jack Morse, *Facebook Isn't the Only Tech Company with Too Much of Your Data*, MASHABLE (Apr. 14, 2018), <https://mashable.com/2018/04/14/google-amazon-facebook-cambridge-analytica/#50O.gYrlzPqW>.

<sup>179</sup> See generally Nicolas P. Terry, *Regulatory Disruption and Arbitrage in Health-Care Data Protection*, 17 YALE J. HEALTH POL'Y L. & ETHICS 143, 173-84 (2017) (noting the consumer healthcare domain is less regulated than the professional domain).

<sup>180</sup> See generally *Privacy and Security Enforcement*, FED. TRADE COMM'N, <https://www.ftc.gov/news-events/media-resources/protecting-consumer-privacy/privacy-security-enforcement> (last visited Oct. 27, 2018).

<sup>181</sup> See Terry, *supra* note 179, at 168-73; see also Nicolas P. Terry & Lindsay F. Wiley, *Liability for Mobile Health and Wearable Technologies*, 25 ANNALS HEALTH L. 62 (2016); Nicolas P. Terry, *Will the Internet of Things Transform Healthcare?*, 19 VAND. J. ENT. & TECH. L. 327 (2016).

<sup>182</sup> 45 C.F.R. pts. 160, 162, 164 (2018).

healthcare domain.<sup>183</sup> For hybrid companies to be drawn into the HIPAA web, it would not be enough for them to merely hold or process personal health information.<sup>184</sup> Rather, the hybrid would have to satisfy the HIPAA Privacy Rule’s definition of “covered entity.”<sup>185</sup> Included in this definition is a “health plan,” which the Act defines as an “individual or group plan that provides, or pays the cost of, medical care.”<sup>186</sup> In short, Prime Health would be covered by HIPAA if it were held to be an “insurer” or a “group health plan.” The former is possible, as discussed below, but the latter is probable.<sup>187</sup> The specifics of HIPAA compliance for group insurance plans<sup>188</sup> should be no surprise to Amazon, as this is the model Amazon currently uses to provide coverage to its employees.<sup>189</sup>

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<sup>183</sup> See, e.g., 45 C.F.R. § 164.502.

<sup>184</sup> A small exception exists for non-healthcare data custodians who hold personal health records who are subject to a special data notification rule. See *Complying with the FTC’s Health Breach Notification Rule*, FED. TRADE COMM’N, <https://www.ftc.gov/tips-advice/business-center/guidance/complying-ftcs-health-breach-notification-rule> (last visited Oct. 27, 2018).

<sup>185</sup> The HIPAA Privacy Rule defines a “covered entity” as follows:

*Covered entity* means:

- (1) A health plan.
- (2) A health care clearinghouse.
- (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

45 C.F.R. § 160.103.

<sup>186</sup> *Id.*

<sup>187</sup> The HIPAA Privacy Rule defines “group health plan” as follows:

Group health plan . . . means an employee welfare benefit plan . . . including insured and self-insured plans, to the extent that the plan provides medical care . . . , including items and services paid for as medical care, to employees or their dependents directly or through insurance, reimbursement, or otherwise, that:

- (1) Has 50 or more participants . . . ; or (2) Is administered by an entity other than the employer that established and maintains the plan.

*Id.*

<sup>188</sup> See, e.g., 45 C.F.R. § 164.504(f).

<sup>189</sup> See AMAZON, BENEFITS ENROLLMENT GUIDE 2017-2018 16-18, [https://amazon.ehr.com/ESS/Client/Documents/BenefitSummaries/AMZ%202017\\_OE\\_ITS\\_FT\\_Guide\\_Final\\_20170130.pdf](https://amazon.ehr.com/ESS/Client/Documents/BenefitSummaries/AMZ%202017_OE_ITS_FT_Guide_Final_20170130.pdf).

While Amazon is capable of achieving HIPAA-class security,<sup>190</sup> its current Alexa-enabled devices are unlikely to survive a HIPAA audit.<sup>191</sup> Further, Prime Health would require a privacy model (and culture) that would be distinct from Amazon's own, and ABJ would need to resist attempts by its partners to cross-market or data-mine using Prime Health data.

### 3. *Insurance, ERISA, and Fiduciary Duties*

Assuming the premise that Prime Health will disintermediate existing health insurers (at least for ABJ employees), the question arises whether it will be considered an "insurer" engaging in the "business of insurance," within the meaning of the McCarran-Ferguson Act,<sup>192</sup> for regulatory purposes. Although that could be a fascinating inquiry and there are some indications that Amazon is entering insurance markets in other countries,<sup>193</sup> this is not a crucial inquiry given the current regulatory model in the U.S.

The McCarran-Ferguson Act reserves insurance regulation to the states.<sup>194</sup> If Prime Health is structured as a fully insured plan (i.e. ABJ pays premiums to a health insurer to cover its employees), it will be subject to diverse state insurance regulations. These include, for example, licensing, benefits, consumer protection, and dispute resolution regulations. However, this would be extremely unlikely if Prime Health is not structured as a self-funded plan in which the employer takes the risk subject to stop-loss reinsurance. In general terms, self-funded plans are viewed as employee benefits subject to the Employee Retirement Income Security Act of 1974 (ERISA).<sup>195</sup>

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<sup>190</sup> See *HIPPA*, AMAZON WEB SERVICES, <https://aws.amazon.com/compliance/hipaa-compliance/> (last visited Oct. 17, 2018).

<sup>191</sup> Jack Murtha, *Amazon's Alexa Really Isn't Ready For Healthcare*, HEALTHCARE ANALYTICS NEWS (May 24, 2018), <http://www.hcanews.com/news/amazons-alexa-really-isnt-ready-for-healthcare>.

<sup>192</sup> See McCarran-Ferguson Act, 15 U.S.C. §§ 1011-15 (2012).

<sup>193</sup> Maria Terekhova, *Amazon Pushes Further into Insurance with its Latest Investment*, BUS. INSIDER (Jan. 5, 2018, 9:20 AM), <https://www.businessinsider.com/amazon-pushes-further-into-insurance-with-its-latest-investment-2018-1>.

<sup>194</sup> 15 U.S.C. §§ 1011-12.

<sup>195</sup> Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406, 88 Stat. 829 (codified as amended in scattered sections of 26 and 29 U.S.C.).

ERISA plays two roles. First, it applies some substantive federal regulation over self-funded plans, such as imposing fiduciary duties on the employer-insurer.<sup>196</sup> Second, ERISA preempts state insurance regulation for self-funded plans,<sup>197</sup> essentially deregulating employers’ self-funded plans. Some of that deregulation was countered by HIPAA Subtitle A and the ACA.<sup>198</sup> A broad preemptive approach to ERISA has been adopted by the United States Supreme Court,<sup>199</sup> and as Congress and the Trump Administration continue to deprecate ACA protections, the ERISA shield may become important again. ERISA (and the continued viability of the ACA) should provide some stable, national framework for the regulation of Prime Health insofar as Prime Health is viewed as an insurer or, more likely, as a self-funded health plan.

### *B. Applicability of State Laws*

As mentioned, pursuant to the McCarran-Ferguson Act, Prime Health will be subject to state insurance regulations if it is structured as a fully insured plan. Outside of insurance regulation, ABJ will also face a broad array of state healthcare-related legislation and regulation requiring navigation.

ABJ’s employees are scattered across the country. Amazon alone has 140 fulfillment centers and a brick-and-mortar presence in an increasing number of states.<sup>200</sup> As their physical presence expanded into more and more states, Amazon began collecting state sales taxes on purchases, albeit often in exchange for tax credits or other state largesse encouraging Amazon to set up shop locally.<sup>201</sup> (In fact,

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<sup>196</sup> 29 U.S.C. § 1104. *See generally* U.S. DEP’T. LAB., EMP. BENEFITS SECURITY ADMIN., UNDERSTANDING YOUR FIDUCIARY RESPONSIBILITIES UNDER A GROUP HEALTH PLAN (2015), <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/publications/understanding-your-fiduciary-responsibilities-under-a-group-health-plan.pdf>.

<sup>197</sup> 29 U.S.C. § 1144.

<sup>198</sup> *See generally* Abbe R. Gluck et al., *ERISA: A Bipartisan Problem for the ACA and the AHCA*, HEALTH AFF.: HEALTH AFF. BLOG (June 2, 2017), <https://www.healthaffairs.org/doi/10.1377/hblog20170602.060391/full/>.

<sup>199</sup> *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 496 (2015).

<sup>200</sup> Dennis Green & Anaele Pelisson, *This Map of Amazon's Warehouse Locations Shows How It's Taking Over America*, BUS. INSIDER (Sept. 27, 2017, 12:14 PM), <http://www.businessinsider.com/amazon-warehouse-locations-in-us-2017-9>.

<sup>201</sup> Thad Rueter, *Amazon to Open Another Distribution Center in Indiana*, DIGITAL COM. 360 (Mar. 27, 2012), <https://www.digitalcommerce360.com/2012/03/27/amazon-open-another-distribution-center-indiana/> (noting \$2 million in tax credits and \$300,000 in training grants from the Indiana Economic Development Corp.).

they stopped relying on the *Quill Corp. v. North Dakota*<sup>202</sup> sales tax loophole long before *South Dakota v. Wayfair, Inc.*<sup>203</sup>) Currently, Amazon collects state sales tax on purchases in all forty-five states that have a statewide sales tax.<sup>204</sup> In his Aspen Institute interview, Atul Gawande noted ABJ employees “are across the entire country.”<sup>205</sup>

Of course, there are broad policy disagreements among the states, creating differences in state laws relating to Medicaid expansion, scope of practice,<sup>206</sup> telemedicine,<sup>207</sup> and prescription drug cost controls.<sup>208</sup> To the extent Prime Health begins to resemble traditional insurers or healthcare providers, ABJ will likely have to contend with a myriad of similar, but not identical, state licensing statutes,<sup>209</sup> regulations,<sup>210</sup> and regulators<sup>211</sup> that may increase the cost of providing interstate care. Judicial regulation of healthcare through tort and contract models is almost exclusively a matter of state law, featuring differences in the standard of care,<sup>212</sup> the

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<sup>202</sup> *Quill Corp. v. North Dakota*, 504 U.S. 298, 305-08 (1992) (finding states could not collect taxes from sellers lacking a physical presence in the state).

<sup>203</sup> *South Dakota v. Wayfair, Inc.*, 138 S. Ct. 2080 (2018) (overruling *Quill Corp.*, 504 U.S. 298).

<sup>204</sup> Chris Isidore, *Amazon to Start Collecting State Sales Taxes Everywhere*, CNN (Mar. 29, 2017, 2:59 PM), <http://money.cnn.com/2017/03/29/technology/amazon-sales-tax/index.html>.

<sup>205</sup> Conversation with Atul Gawande, *supra* note 103.

<sup>206</sup> See *Credentialing, Licensing, and Education*, NAT’L CTR. FOR COMPLEMENTARY AND INTEGRATIVE HEALTH, <https://nccih.nih.gov/health/decisions/credentialing.htm> (last visited Oct. 28, 2018) (discussing state to state variations in credentialing and licensing standards); see also *N.C. State Bd. of Dental Exam’rs v. FTC*, 135 S. Ct. 1101 (2015).

<sup>207</sup> See, e.g., *Telemedicine Laws and Developments: A State-by-State Analysis*, BECKER’S HOSP. REV. (Aug. 22, 2014), <https://www.beckershospitalreview.com/healthcare-information-technology/telemedicine-laws-and-developments-a-state-by-state-analysis.html> (last visited Nov. 21, 2018).

<sup>208</sup> See, e.g., *Health*, NAT’L CONF. OF ST. LEGISLATURES, <http://www.ncsl.org/research/health.aspx> (last visited November 4, 2018).

<sup>209</sup> See, e.g., IND. CODE §§ 16-18-2-179, 16-21-2, 25-22.5-1-1.1, 27-8-10-1 (2018).

<sup>210</sup> See, e.g., 844 IND. ADMIN. CODE 5-1-1 et seq. (2018).

<sup>211</sup> See, e.g., IND. CODE § 25-22.5-2-1; see also *Bever v. State Bd. of Registration for Healing Arts*, No. WD 57880, 2001 WL 68307 (Mo. Ct. App. Jan. 30, 2001) (state board disciplinary inquiry into alleged substandard care).

<sup>212</sup> Compare *Sheeley v. Mem’l Hosp.*, 710 A.2d 161 (R.I. 1998) (national standard of care), with *Hagedorn v. Peterson*, 690 N.W.2d 84 (Iowa 2004) (retaining the “locality” rule).

disclosure model for informed consent,<sup>213</sup> and the rules defining the “corporate” liability of healthcare entities.<sup>214</sup>

Large corporations operating in multiple states will generally recognize and “price-in” such differences between state laws. This is expected. However, state laws that have anti-competitive effects may have more of a surprising result. Two laws that qualify are the corporate practice of medicine doctrine (“CPM”) and certificate of need laws (“CON”).

### *1. Corporate Practice of Medicine Doctrine*

The CPM doctrine is an offshoot of the historical licensing of persons in the “practice of medicine.”<sup>215</sup> Corporate entities such as HMOs did not enter the healthcare provider space until the 1970s, and corporate consolidation of healthcare entities did not become pronounced until the 1980s.<sup>216</sup> Not surprisingly, the licensing processes and criteria that developed in the late nineteenth century were framed by and for physicians and not for then unforeseen clinicians such as nurse practitioners or healthcare corporate entities.<sup>217</sup>

Broadly stated, the CPM doctrine prohibits corporations from either practicing medicine (a variant is to require entities to be owned by physicians) or employing physicians to do the same. In contemporary practice, the justifications for the continued existence of the doctrine are the primacy of individual physician judgment<sup>218</sup> and quality of care.<sup>219</sup> Perhaps dubious policy justifications aside, one of

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<sup>213</sup> Compare *Largey v. Rothman*, 540 A.2d 504 (N.J. 1988) (prudent patient standard), with *Eady v. Lansford*, 92 S.W.3d 57 (Ark. 2002) (physician standard), and IND. CODE §§ 34-18-12-2 to -3 (rebuttable presumption of consent from signing consent form).

<sup>214</sup> Compare *Larson v. Wasemiller*, 738 N.W.2d 300 (Minn. 2007) (explaining the limited duty of “negligent credentialing”), with *Thompson v. Nason Hosp.*, 591 A.2d 703, 707-08 (Pa. 1991) (explaining the broad application of corporate negligence). See generally Barry R. Furrow, *Enterprise Liability and Health Care Reform: Managing Care and Managing Risk*, 39 ST. LOUIS U. L.J. 79 (1994).

<sup>215</sup> See generally William C. Tait, *The Legal Definition of the Practice of Medicine*, 2 CAL. ST. J. MED. 119, 119–21 (1904).

<sup>216</sup> See PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 428-36 (1982).

<sup>217</sup> See *id.* at 102-11.

<sup>218</sup> *Corporate Practice of Medicine*, MED. BOARD. CAL., [http://www.mbc.ca.gov/Licensees/Corporate\\_Practice.aspx](http://www.mbc.ca.gov/Licensees/Corporate_Practice.aspx) (last visited Nov. 5 2018) (“The policy . . . is intended to prevent unlicensed persons from interfering with or influencing the physician's professional judgment.”).

<sup>219</sup> For example, California considers the following to be unlicensed practice of medicine if performed by an unlicensed person:

the major problems with CPM is that the doctrine varies on a state-by-state basis. In the words of the Supreme Court of Illinois:

[S]ome jurisdictions refused to adopt the prohibition against the corporate practice of medicine altogether. . . . [O]ther jurisdictions determined that the corporate practice of medicine doctrine is inapplicable to nonprofit hospitals and health associations on the basis that the public policy arguments supporting the doctrine do not apply to physicians employed by charitable institutions. . . . [T]he remainder of jurisdictions have determined that the prohibition against the corporate practice of medicine does not apply to hospitals which employ physicians because hospitals are authorized under other laws to provide medical treatment to patients.<sup>220</sup>

According to Nicole Huberfeld, “[t]he corporate practice of medicine doctrine is a relic; a physician-centric guild doctrine that is at best misplaced, and at worst obstructive, in the present incarnation of the American healthcare system.”<sup>221</sup> It is, however, just the kind of relic that a radically restructured hybrid health entity may have to navigate.

## 2. *Certificate of Need Laws*

CON laws are another historic relic. The Hospital Survey and Construction Act, better known as the Hill–Burton Act of 1946,<sup>222</sup> was partly designed to modernize the post-war hospital system without overbuilding in particular areas.<sup>223</sup>

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Determining what diagnostic tests are appropriate for a particular condition.

Determining the need for referrals to, or consultation with, another physician/specialist.

Responsibility for the ultimate overall care of the patient, including treatment options available to the patient.

Determining how many patients a physician must see in a given period of time or how many hours a physician must work.

*Id.*

<sup>220</sup> *Carter-Shields v. Alton Health Inst.*, 777 N.E.2d 948, 956 (Ill. 2002).

<sup>221</sup> Nicole Huberfeld, *Be Not Afraid of Change: Time to Eliminate the Corporate Practice of Medicine Doctrine*, 14 HEALTH MATRIX 243, 243-45 (2004).

<sup>222</sup> Hospital Survey and Construction (Hill-Burton) Act, Pub. L. No. 79-725, 60 Stat. 1040 (1946) (codified as amended at 42 U.S.C. §§ 291 to 291o1-1 (2012)).

<sup>223</sup> *CON-Certificate of Need State Laws*, NAT’L CONF. OF ST. LEGISLATURES (Aug. 17, 2018), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx>. See generally *The Hospital Survey and Construction Act*, 132 J. AM. MED. ASS’N 148 (1946).



States responded by passing CON laws designed to scrutinize proposals to build healthcare facilities. As explained by the National Conference of State Legislatures, “[t]he basic assumption underlying CON regulation is that excess capacity stemming from overbuilding of health care facilities results in health care price inflation.”<sup>224</sup> The federal construct expired decades ago, yet most states have maintained some type of legislative or regulatory structure for determining whether proposed healthcare construction qualifies for a certificate of need.<sup>225</sup>

The ABJ partners should rightly conclude that CON laws are anticompetitive. As noted by the FTC, “[b]y interfering with the market forces that normally determine supply of services, CON laws can suppress competition and shield incumbent health care providers from competition from new entrants.”<sup>226</sup> The Court of Appeals for the Fourth Circuit, however, is less receptive to the argument that CON laws are anticompetitive:

Appellants’ free market arguments also overlook the fact that the health care market has its own idiosyncrasies. . . . Squeezed by insurers, regulation, and obligations to provide indigent care at a financial loss, providers lack the customary freedom of a seller of services to set its price. Unprofitable but vital medical services do not reap providers the usual market rewards. Many of the classic features of a free market are simply absent in the health care context, and that fact counsels caution when courts are urged to dismantle regulatory efforts to counter perceived gaps and inefficiencies in the healthcare market.<sup>227</sup>

A company like Amazon that is accustomed to large tax breaks from states hoping to attract new fulfillment centers or even its second headquarters<sup>228</sup> would no

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<sup>224</sup> *CON-Certificate of Need State Laws*, *supra* note 223.

<sup>225</sup> *See id*; *see also* Matthew D. Mitchell & Christopher Koopman, *40 Years of Certificate-of-Need Laws Across America*, MERCATUS CTR. AT GEO. MASON U., (Sept. 27, 2016), <https://www.mercatus.org/publication/40-years-certificate-need-laws-across-america>.

<sup>226</sup> FED. TRADE COMM’N, JOINT STATEMENT OF THE FEDERAL TRADE COMMISSION AND THE ANTITRUST DIVISION OF THE U.S. DEPARTMENT OF JUSTICE TO THE VIRGINIA CERTIFICATE OF PUBLIC NEED WORK GROUP (2015), [https://www.ftc.gov/system/files/documents/advocacy\\_documents/joint-statement-federal-trade-commission-antitrust-division-u.s.department-justice-virginia-certificate-public-need-work-group/151026ftc-dojstmtva\\_copn-1.pdf](https://www.ftc.gov/system/files/documents/advocacy_documents/joint-statement-federal-trade-commission-antitrust-division-u.s.department-justice-virginia-certificate-public-need-work-group/151026ftc-dojstmtva_copn-1.pdf).

<sup>227</sup> *Colon Health Ctrs. of Am., LLC v. Hazel*, 813 F.3d 145, 158 (4th Cir. 2016) (challenging unsuccessfully Virginia’s CON law invoking the dormant commerce clause).

<sup>228</sup> Elizabeth Weise, *Amazon Second Headquarters Search Has Become a Cultural Meme, A Year After It Began*, USA TODAY (Sept. 5, 2018, 5:00 AM), <https://www.usatoday.com/story/tech/news/2018/09/05/amazon-hq-2-search-has-become-cultural-meme-year-after-began/1180525002/>.

doubt be bewildered when faced with a state requirement that it justify the construction of Prime Health facilities.

## V

### (HOW) SHOULD HYBRID HEALTHCARE BE REGULATED?

The preceding observations about the application of federal and state regulatory models to hybrid healthcare entities is primarily descriptive. Due to pragmatic constraints, I have assumed that these novel entities will not be met by a new all-embracing regulatory model. After all, it is far too early to predict what the hybrids will look like or whether they will be sufficiently similar to make common regulation even possible.

Still, such a pragmatic conclusion conceals some potential concerns. For example, Frank Pasquale argues that “[major digital firms] are no longer market participants. Rather, in their fields, they are market makers, able to exert regulatory control over the terms on which others can sell goods and services.”<sup>229</sup> He sees an even more dystopian regulatory future as these firms “aspire to displace more government roles over time, replacing the logic of territorial sovereignty with functional sovereignty.”<sup>230</sup> However, the regulators are in retreat. Almost a generation of work building robust health insurance regulation culminating in the ACA and responsible consumer protection through the Consumer Financial Protection Bureau seems to be running on life support.<sup>231</sup>

Some of the hurdles (for example, CPM and CON) that Prime Health may have to navigate are state laws that themselves have anticompetitive effects. However, the more important competitive question may be how major technology companies themselves impact markets. In August 2018, Amazon became the second company to reach a trillion-dollar market valuation,<sup>232</sup> a few weeks after Apple

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<sup>229</sup> Frank Pasquale, *From Territorial to Functional Sovereignty: The Case of Amazon*, L. & POL. ECON. (Dec. 6, 2017), <https://lpeblog.org/2017/12/06/from-territorial-to-functional-sovereignty-the-case-of-amazon/>.

<sup>230</sup> *Id.*

<sup>231</sup> See, e.g., Jonathan Oberlander, *The Republican War on Obamacare—What Has It Achieved?*, 379 NEW ENG. J. MED. 703, (Aug. 23, 2018); Alan Rappeport, *What’s in a Name? Consumer Bureau to Find Out*, N.Y. TIMES (Jun. 12, 2018), <https://www.nytimes.com/2018/06/12/business/consumer-protection-bureau-mulvaney.html>.

<sup>232</sup> Laura Stevens & Amrith Ramkumar, *Amazon Hits \$1 Trillion Valuation*, WALL ST. J., (Sept. 4, 2018, 4:11 PM), <https://www.wsj.com/articles/amazon-hits-1-trillion-valuation-1536075734>.

achieved the same feat.<sup>233</sup> The healthcare ambitions of the two largest companies have not been lost on incumbents. Indeed, the CVS-Aetna merger,<sup>234</sup> itself an attempt to remake healthcare delivery, was likely partially driven by the threat of Prime Health<sup>235</sup> and the government’s blocking of horizontal mergers between insurers.<sup>236</sup> The combined company could leverage CVS’s retail health clinics to provide low cost primary care and, by making it easier to reach patients, enable preventative care.<sup>237</sup> This would enable Aetna to partially disintermediate physician practices, particularly those who refer patients to their networked (and expensive) secondary and tertiary care providers.

Healthcare has experienced unprecedented levels of deal making in the years following the passage of the ACA. Between 2013 and 2017, almost twenty percent of U.S. hospitals merged with or were acquired by another hospital.<sup>238</sup> The result is

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<sup>233</sup> Sara Salinas, *Apple Hangs onto Its Historic \$1 Trillion Market Cap*, CNBC (Aug. 2, 2018, 11:48 AM), <https://www.cnbc.com/2018/08/02/apple-hits-1-trillion-in-market-value.html>.

<sup>234</sup> Press Release, CVS Health, *CVS Health Announces Management Team for Combined Company Following Close of Aetna Acquisition Transaction* (June 6, 2018), <https://cvshealth.com/newsroom/press-releases/cvs-health-announces-management-team-combined-company-following-close-aetna>.

<sup>235</sup> Reed Abelson, *As Health Care Changes, Insurers, Hospitals and Drugstores Team Up*, N.Y. TIMES, (Nov. 26, 2017), <https://www.nytimes.com/2017/11/26/health/health-care-hospitals-insurers.html?>.

<sup>236</sup> Compare Press Release, Aetna, *Aetna and Humana Mutually End Merger Agreement* (Feb. 14 2017), <https://news.aetna.com/news-releases/aetna-and-humana-mutually-end-merger-agreement/>, and *Delaware Judge Denies Anthem Injunction, Effectively Ending Cigna Merger*, CNBC (May 12, 2017, 7:02 AM), <https://www.cnbc.com/2017/05/12/delaware-judge-denies-anthem-injunction-effectively-ending-cigna-merger.html>, with Cecilia Kang & Edmund Lee, *AT&T-Time Warner Deal Approval Gets Justice Department Challenge*, N.Y. TIMES (July 12, 2018), <https://www.nytimes.com/2018/07/12/business/justice-department-plans-appeal-of-att-time-warner-merger-approval.html> (showing vertical mergers seem to trouble regulators less).

<sup>237</sup> Paul R. La Monica, *What the CVS-Aetna Deal Means for Consumers*, CNN (Dec. 5, 2017, 7:51 AM), <http://money.cnn.com/2017/12/04/investing/cvs-aetna-consumers/index.html>.

<sup>238</sup> Steven Findlay, *Can A Community Hospital Stay True to Its Mission After Sale to Large Corporation?*, KAISER HEALTH NEWS, (July 23, 2018), <https://khn.org/news/can-a-community-hospital-stay-true-to-its-mission-after-sale-to-large-corporation/>; see also *US Health Services Deals Insights: Q3 2018*, PwC, <https://www.pwc.com/us/en/health-industries/publications/health-services-quarterly-deals-insights.html> (last visited Nov. 5, 2018); Melanie Evans & Anna W. Mathews, *Hospital Giants in Talks to Merge to Create Nation’s Largest Operator*, WALL ST. J. (Dec. 10, 2017, 8:15 PM), <https://www.wsj.com/articles/hospital-giants-in-talks-to-merge-to-create-nations-largest-operator-1512921420>; Keshia Hannam, *Ascension and Providence St. Joseph in Talks to Form U.S.’s Largest Hospital Operator*, FORTUNE (Dec. 11, 2017), <http://fortune.com/2017/12/11/ascension-providence-merger/>.

that healthcare is arguably already over-concentrated and requires far more regulatory scrutiny to avoid declines in quality, cost containment,<sup>239</sup> and local services.<sup>240</sup>

A very real question arises as to how antitrust regulators will react to large hybrid companies entering the healthcare space. Amazon's competitors and analysts act as though the company holds monopoly power. For example, after a report that Amazon had obtained wholesale pharmacy licenses, the stock prices of other drug distribution companies plunged.<sup>241</sup> But neither this "Amazon Effect" nor the company's unprecedented wealth and market share make Amazon a dictionary definition monopoly.<sup>242</sup> Indeed, it prompted Lina Khan to argue that the prevailing "antitrust doctrine [that] views low consumer prices, alone, to be evidence of sound competition"<sup>243</sup> is a flawed model for assessing modern businesses such as Amazon. Khan argues that "a company's power and the potential anticompetitive nature of that power cannot be fully understood without looking to the structure of a business and the structural role it plays in markets."<sup>244</sup>

Khan's observations are particularly salient for Prime Health. Will success in reducing costs relative to traditional healthcare businesses give ABJ a pass or perhaps even some sort of award for finally bending the healthcare cost curve? Or will incumbents successfully argue that (allegedly) predatory pricing, customer data leveraging, and horizontal *and* vertical integration require enhanced regulatory scrutiny? It appears that the current Department of Justice position is that there is no evidence that the large technology companies are harming competition.<sup>245</sup>

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<sup>239</sup> Brent D. Fulton, *Health Care Market Concentration Trends in the United States: Evidence and Policy Responses*, 36 HEALTH AFF. 1530 (2017).

<sup>240</sup> Casey Ross, *Paying More and Getting Less: As Hospital Chains Grow, Local Services Shrink*, STAT (Jan. 24, 2018), <https://www.statnews.com/2018/01/24/hospital-chains-services-consolidation/>.

<sup>241</sup> Rani Molla, *Amazon's Move into Wholesale Pharmaceuticals Sent Pharmacy Stocks Plunging*, RECODE (Oct. 27, 2017, 12:00 PM), <https://www.recode.net/2017/10/27/16559284/amazon-pharmaceutical-wholesale-stocks-plunging-amzn-cvs>.

<sup>242</sup> Coren, *supra* note 57.

<sup>243</sup> Lina M. Khan, *Amazon's Antitrust Paradox*, 126 YALE L.J. 710, 716 (2017).

<sup>244</sup> *Id.* at 716-17.

<sup>245</sup> See David McLaughlin, *Trump Antitrust Chief Says No Sign of Competitive Harm from Tech*, BLOOMBERG (Sept. 28, 2018, 12:56 PM), <https://www.bloomberg.com/news/articles/2018-09-28/trump-antitrust-chief-says-no-sign-of-competitive-harm-from-tech>.

Antitrust aside, there are (or should be) three specific concerns regarding the Prime Health construct imagined herein. First, earlier it was noted how some technology firms working in the health space have apparently been granted special treatment through the FDA’s Pre-Cert program.<sup>246</sup> Overall, this seems to be an appropriate way to explore nimbler models of regulation that are better suited to rapidly innovating products. However, as the FDA’s use of Pre-Cert, mobile app enforcement discretion,<sup>247</sup> and other expedited regulatory processes (for example, *de novo* review applied to the ECG app in the new Apple Watch Series 4<sup>248</sup>) expands, the FDA will need to publish stronger guardrails to maintain our trust in the agency’s safety and efficacy reviews.

Second, as discussed above, there has always been a path-dependent, almost accidental quality to the involvement of employers in providing access to healthcare for their employees.<sup>249</sup> This structure can cause concerns or even conflicts of interest when employers opt to retain the insurance risk and self-fund their employees’ health insurance and, for example, use an insurer for ASO. Pre-ACA ERISA protections were designed to cabin some of the greatest risks associated with direct employer involvement in benefits decisions.<sup>250</sup> Similarly, the HIPAA Privacy Rule has specific provisions applying to employers who provide health insurance,<sup>251</sup> including the requirement that such employers build data “walls” between people or departments dealing with health insurance and, say, human resources.<sup>252</sup> Prime Health (and other businesses building out direct care models) may, however, involve building a far closer relationship between employers and the provision of healthcare to employees. There is danger of information acquired for healthcare purposes surfacing

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<sup>246</sup> See *supra* note 172 and accompanying text.

<sup>247</sup> *Examples of Mobile Apps for Which the FDA Will Exercise Enforcement Discretion*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medicaldevices/digitalhealth/mobilemedicalapplications/ucm368744.htm> (last updated Aug. 1, 2016).

<sup>248</sup> U.S. Food & Drug Admin., Classification Order on ECG App (Sept. 11, 2018), *available at* [https://www.accessdata.fda.gov/cdrh\\_docs/pdf18/DEN180044.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180044.pdf).

<sup>249</sup> Conversation with Atul Gawande, *supra* note 103.

<sup>250</sup> *C.f.* Karl Polzer & Patricia A. Butler, *Employee Health Plan Protections Under ERISA*, 16 HEALTH AFF. 93 (1997) (stating that ERISA was designed to establish uniform federal standards for employee benefit plans that are offered through private employers and unions).

<sup>251</sup> 45 C.F.R. § 164.504 (2018).

<sup>252</sup> 45 C.F.R. § 164.504(f)(2).

elsewhere—as occurred, for example, during the outing of the AOL “distressed babies.”<sup>253</sup>

Third, and perhaps most importantly, there are growing concerns about how technology firms are subject to relatively little data protection regulation. This is especially alarming considering that technology companies will edge closer to our specific clinical data rather than “merely” aggregate healthcare data. The U.S. has a tradition of exceptional protection for healthcare data, surpassing that provided for data in other domains.<sup>254</sup> Because the regulation is triggered by domain participants rather than data type, technology companies are not required to protect healthcare data to the same degree as healthcare providers.<sup>255</sup> Often, domain-specific regulation has invited regulatory arbitrage.<sup>256</sup> Recently, Apple CEO Tim Cook went so far as to criticize some of his technology company competitors as a “data industrial complex” engaged in surveillance.<sup>257</sup>

Our lack of long-term, imaginative policymaking combined with narrow, domain-specific legislation has created a fragmented, often incoherent regulatory environment. The optimal solution to the data protection issues raised by hybrid healthcare lies in the enactment of a U.S. analogue to the General Data Protection Regulation (GDPR), but the odds of that happening are low.<sup>258</sup> Modern legislation or regulation tends to be of the band-aid variety lest markets should become jittery, while building modern legislative and regulatory structures designed to deal with contemporary problems seems anathema to our political processes. Even the expansive California Consumer Privacy Act of 2018, the single most advanced, general (i.e., not domain-specific) privacy law enacted in the U.S. in a generation,<sup>259</sup> is embroiled in some debate as to whether it does or should apply to healthcare

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<sup>253</sup> See Amy D. Sorkin, *Whose Distressed Baby Is It?*, NEW YORKER (Feb. 11, 2014), <https://www.newyorker.com/news/amy-davidson/whose-distressed-baby-is-it>.

<sup>254</sup> See generally Terry, *supra* note 179, at 168-73.

<sup>255</sup> *Id.*

<sup>256</sup> See generally *id.* at 173-84.

<sup>257</sup> Natasha Lomas, *Apple’s Tim Cook Makes Blistering Attack on the ‘Data Industrial Complex,’* TECHCRUNCH (Oct. 24, 2018), <https://techcrunch.com/2018/10/24/apples-tim-cook-makes-blistering-attack-on-the-data-industrial-complex/>.

<sup>258</sup> See General Data Protection Regulation (GDPR), Regulation 2016/679, 2016 O.J. (L119) 1 (EU). See generally David Meyer, *GDPR Attacks: First Google, Facebook, Now Activists Go After Apple, Amazon, LinkedIn*, ZDNET (May 29, 2018, 1:44 PM), <https://www.zdnet.com/article/gdpr-attacks-first-google-facebook-now-activists-go-after-apple-amazon-linkedin/>.

<sup>259</sup> California Consumer Privacy Act of 2018, CAL. CIV. CODE §§ 1798.100 to 1798.198 (West 2018).

providers.<sup>260</sup> Notwithstanding, other recent California legislation dealing with the cybersecurity of connected devices does appear to cover the healthcare “information of things” that are being embraced by hybrid healthcare providers.<sup>261</sup> Although there has been some current interest in federal data protection legislation,<sup>262</sup> it is difficult to imagine a current Congressional majority that would favor anything more rigorous than the relatively light regulatory model involving enforceable codes of conduct that was proposed by the Obama Administration in 2015.<sup>263</sup>

There is much to like about the companies behind hybrid healthcare. We are enthralled by their innovation and the optimism they bring into the space. For now, we may even trust them (or at least some of them). But the fundamental regulatory truth is that we lack a “Plan B” if they decide to be evil.<sup>264</sup>

### CONCLUSION

As both Microsoft founder Bill Gates<sup>265</sup> and President Donald Trump<sup>266</sup> have remarked, healthcare is “complicated.” The *Economist* notes that “[i]t is worth remembering that the prospect of technology firms transforming health care has been

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<sup>260</sup> See S.B. No. 1125, 2017-2018 Leg., Reg. Sess. (Cal. 2018).

<sup>261</sup> S.B. No. 327, 2017-2018 Leg., Reg. Sess. (Cal. 2018).

<sup>262</sup> *Examining Safeguards for Consumer Data Privacy Before the Senate Committee on Commerce, Science, and Transportation*, 115th Cong. (2018) (announcement of the hearing available at <https://www.commerce.senate.gov/public/index.cfm/hearings?ID=2FF829A8-2172-44B8-BAF8-5E2062418F31>).

<sup>263</sup> See Dan Tynan, *Silicon Valley Finally Pushes for Data Privacy Laws at Senate Hearing*, GUARDIAN (Sept. 26, 2018, 7:33 PM), <https://www.theguardian.com/technology/2018/sep/26/silicon-valley-senate-commerce-committee-data-privacy-regulation>; see also David McCabe, *Tech Companies Want Privacy Rules, But on Their Own Terms*, AXIOS (Sept. 26, 2018), <https://www.axios.com/tech-telecom-support-federal-privacy-legislation-but-not-gdpr-or-california-law-a8844666-7e1b-4bec-beac-30377e54e70e.html>. See generally Nicolas P. Terry, *Should Health Lawyers Pay Attention to the Administration’s Privacy Bill?*, HEALTH AFF.: HEALTH AFF. BLOG (Mar. 13, 2015), <https://www.healthaffairs.org/doi/10.1377/hblog20150313.045523/full/>.

<sup>264</sup> Kate Conger, *Google Removes ‘Don’t Be Evil’ Clause from Its Code of Conduct*, GIZMODO (May 18, 2018, 5:31 PM), <https://gizmodo.com/google-removes-nearly-all-mentions-of-dont-be-evil-from-1826153393>.

<sup>265</sup> Megan Thielking, *Bill Gates Is Glad Amazon Is Getting into Health Care—But Cautions It’s Complicated*, STAT (Apr. 30, 2018), <https://www.statnews.com/2018/04/30/bill-gates-amazon-dimon-buffet/>.

<sup>266</sup> Kevin Liptak, *Trump: ‘Nobody Knew Health Care Could be So Complicated,’* CNN (Feb. 28, 2017, 4:10 AM), <https://www.cnn.com/2017/02/27/politics/trump-health-care-complicated/index.html>.

heralded in the past, only to disappoint.”<sup>267</sup> Not surprisingly, commentators have greeted the new venture with equal amounts of skepticism<sup>268</sup> and cautious optimism.<sup>269</sup>

The U.S. healthcare ecosystem and ecosystem are so complex that outsiders making even slight contact will face indeterminacies and barriers to entry that have their roots in both market and regulatory failures. As hybrid entities, particularly Amazon, enter the healthcare space and offer healthcare financing and healthcare services, they will also be sucked into healthcare’s regulatory morass.

Prime Health and the other hybrid insurgents will also experience pushback and even competition from incumbents. We will see more concentrations, primarily of the vertical type like the CVS-Aetna merger.<sup>270</sup> Others may be combinations of insurers and providers,<sup>271</sup> while others yet may be combinations of insurers, PBMs, and health systems.<sup>272</sup> There will also be insurgents other than technology companies.<sup>273</sup> However, in the case of the traditional healthcare entities, some skepticism is appropriate as to whether they will change their ways or whether they are merely building defensive positions by combining two different levels of

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<sup>267</sup> *Surgical Intervention*, *supra* note 18, at 59, 60.

<sup>268</sup> See, e.g., Anna W. Mathews et al., *JP Morgan Plan Frets Some*, WALL ST. J., Feb. 4, 2018, at B2; Margot Sanger-Katz & Reed Abelson, *Can Amazon and Friends Handle Health Care? There’s Reason for Doubt*, N.Y. TIMES (Jan. 30, 2018), <https://www.nytimes.com/2018/01/30/upshot/can-amazon-and-friends-handle-health-care-theres-reason-for-doubt.html>; Spencer Soper & Caroline Chen, *Amazon Hasn’t Figured Out Drugstores Yet. But It Will Have To*, BLOOMBERG (Dec. 18, 2017, 7:00 AM), <https://www.bloomberg.com/news/articles/2017-12-18/amazon-hasn-t-figured-out-drug-stores-yet-but-it-will-have-to>.

<sup>269</sup> See, e.g., David Blumenthal, *Can Three of America’s Most Innovative Business Minds Really Transform Health Care?*, HILL (Feb. 5, 2018, 7:30 AM), <http://thehill.com/opinion/healthcare/372074-can-three-of-americas-most-innovative-business-minds-really-transform>.

<sup>270</sup> See generally PWC HEALTH RES. INST., *THE NEW HEALTH ECONOMY IN THE AGE OF DISRUPTION: NOVEL COMBINATIONS ATTEMPT TO REMAKE THE HEALTH SYSTEM* 2-5 (Apr. 2018), <https://www.pwc.com/us/en/health-industries/health-research-institute/pdf/pwc-hri-the-new-health-economy-in-the-age-of-disruption.pdf>.

<sup>271</sup> David Blumenthal, *Is M&A the Cure for a Failing Health Care System?*, HARV. BUS. REV. (Dec. 14, 2017), <https://hbr.org/2017/12/is-ma-the-cure-for-a-failing-health-care-system>.

<sup>272</sup> Abelson, *supra* note 235.

<sup>273</sup> John Bowden, *Walmart in Early Talks to Buy Humana: Report*, HILL (Mar. 29 2018, 7:50 PM), <http://thehill.com/policy/healthcare/380944-walmart-in-early-acquisition-talks-with-humana-report>.



healthcare entity to increase customer lock-in. As the *New York Times* opined, “[they’re] taking a zebra and a zebra. . . . What they want to become is a unicorn.”<sup>274</sup>

Given its corporate provenance, Prime Health cannot, and indeed should not, take the path well-trodden. As the ACA limps along, we will not see attempts at major health reform any time soon. This is the time for those with extraordinary market power to step forward, to be audacious and to design a true functioning healthcare marketplace. If Prime Health fails, it will lend support to those who argue that consumer-directed and competitive solutions do not work. If it succeeds, Prime Health’s architects will be elevated to the health policy Parthenon to stand next to Otto von Bismarck and William Beveridge.

David Blumenthal’s qualified enthusiasm seems to strike the appropriate tone: “The excitement about these . . . bold new health care arrangements says as much about the desperation with our current health care systems as it does about the promise of the mergers themselves.”<sup>275</sup> Hybrid healthcare, particularly Prime Health, may well be remembered as a final attempt to make employer-provided healthcare affordable and sustainable when the better path forward is arguably for employers to persuade the federal government that employment-based insurance is not the answer; the preferable solution is government-provided insurance. However, until that epitaph is written, it will be a fascinating journey to observe.

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<sup>274</sup> Reed Abelson, *Hospital Giants Vie for Patients in Effort to Fend Off New Rivals*, N.Y. TIMES (Dec. 18, 2017), <https://www.nytimes.com/2017/12/18/health/hospitals-mergers-patients.html>? (quoting Thomas Cassels, a consultant at the Advisory Board).

<sup>275</sup> Blumenthal, *supra* note 271.